OFFICE OF GENERIC DRUGS

Procedures for Post-Approval Commitment Tracking in the Office of Generic Drugs

CONTENTS

PURPOSE

- This MAPP describes procedures to be used by staff in the Office of Generic Drugs (OGD) to process, verify, and track Post-Approval Commitments (PAC) via the Post-Approval Commitment Tracking System (PACT).

BACKGROUND

- It is the policy of the Office of Generic Drugs (OGD) not to withhold approval of an application because of information and/or data that can be obtained after approval. As a condition of approval, an applicant may agree to a Post-Approval Commitment (PAC) to provide specific information to the Agency. OGD will follow up with applicants regarding any issues related to a PAC.

  In addition to commitments agreed to before approval, after approval, the Agency may ask for additional commitments to provide information to further address the safety or effectiveness of the drug product.

  Failure to provide information, data, or changes as agreed to in the PAC may affect the Agency's previous conclusions about the safety or effectiveness of the drug product. OGD staff will keep track of all PACs to ensure that the commitments are addressed in a timely manner.

  This MAPP does not address postmarketing approval studies or phase IV studies under section 506B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356b),

nor does it address the stability commitments for chemistry, manufacturing and controls information on stability data from routine stability testing programs under the stability protocol(s) agreed to in the ANDA.

REFERENCES

- 21 CFR 314.81 Other Postmarketing Reports

DEFINITIONS

- Centerwide Oracle-based Management Information System (COMIS): a tool used by FDA staff to track information about the receipt and review status of new drug applications and, in particular for OGD, abbreviated new drug applications (ANDA).
- MasterQue: a program used by OGD staff to track the progress of ANDA reviews.
- OGD Standard Letters System (OGDSL): a Web-based program that catalogs and generates standardized letters and forms used by OGD project managers (PM) for communication and documentation.
- Post-Approval Commitment (PAC): an agreement with the sponsor of an ANDA made before approval to provide data, information, and changes after a product has been approved for marketing. A commitment can also be made after the application has been approved. The commitments typically involve chemistry, manufacturing and controls. Some examples include, but are not limited to, methods validation,[1] dissolution data, finalization of specifications, and scoring commitments.
- Post-Approval Commitment Tracking (PACT) Program: a program used by OGD PMs to track the status of PACs.

POLICY

- Each team's PM will track all PACs relating to the team, which includes tracking the progress of each commitment until all obligations to the Agency have been satisfied.
- Additional OGD staff members will also track PACs as necessary.
- The reviewer and the Team Leader (TL) will conduct a primary and secondary review, respectively, on the materials submitted by the applicant to determine if the

[1] MAPP 5221.1 Requesting Methods Validation for ANDAs

commitment has been satisfied. This process will be handled according to review policies and procedures in effect at the time of submission.

RESPONSIBILITIES AND PROCEDURES

OGD Project Managers will:

- Document the PAC in MasterQue including the date of the submission that contains the commitment and a summary of the commitment.

- Use the PACT program to enter the specific commitment for the ANDA. The date the commitment was entered into PACT should correspond to the date of the submission that contains the commitment. In the case of a commitment made before approval, the date assigned should be the date of the most recent chemistry amendment submission. For detailed instructions, see Attachment A, "Operating the PACT System."

- When generating an approval letter, check for outstanding commitment(s) and add appropriate language outlining the PAC obligation(s). See the OGDSL for sample letters.

- When the applicant submits material to fulfill the commitment, document the submission in the PACT program. After review is completed, document the outcome of the review in the PACT program. If the submission fulfills all the obligations in the commitment, indicate the date of fulfillment and close out the commitment in the PACT program.

- For commitments involving methods validation, verify with review chemists periodically to determine if it has been completed.

- When a commitment is made after the approval of an application, add a PAC to the PACT program for the appropriate submission, then track the commitment as usual using the PACT program.

- If there has been no evidence of sufficient effort made after one year (or another time frame as appropriate) to satisfy the commitments made in a PAC, generate a Dunner Letter for failure to complete a PAC. See the OGDSL for a sample letter.

OGD Reviewer will:

- Review and verify that the information provided by the applicant regarding the PAC is adequate. Once review is complete, whether adequate or deficient, provide the completed review to the TL and PM.

PACT Coordinator will:

- Print out and distribute the PACT report generated from COMIS every 3 months. See Attachment B for instructions.

- Print out and distribute the methods validation status report every 3 months.

- Provide assistance as needed for PACT related questions and issues.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

ATTACHMENT A

Operating the PACT System

Post-Approval Commitment Tracking (PACT) System

Contents:

A. Introducing the PACT System

The PACT system is used to track studies that applicants commit to undertake or commitments for changes in connection with an approved or nearly approved original application or supplement. A commitment may be made before or after approval of the application.

B. Accessing the PACT System

Double-click the PACT icon on your desktop. This will bring you to the logon screen. Enter your Oracle Username and Password in the appropriate fields. Click the Connect button.

The PACT Data Entry screen will appear.

If you get the "Cannot run the PACT Data Entry form. No privileges" message, contact your IT focal point to request access.

C. Using the PACT System

Adding a commitment

1. On the PACT main screen, click the GO TO PACT Linking button at the bottom of the screen.

2. Enter the ANDA number in the Application field. Add additional search criteria as needed in the fields for Doc Type, Letter Date, Sponsor Applicant, and Established Name.

3. Click the Query Documents button. A list of all submissions defined by the search criteria will appear.

4. a) Select the appropriate submission and select *yes* under the PACT column.
   b) Click the Go To PACT button.

5. Type the ANDA number in the Application No field and hit enter. Do not click the LOV (eyeglass) button.

6. a) The List of Values (LOV) button attached to the right of the Document field is used to list all the post-approval requests that exist for the application. Click on that LOV button.
   b) Select the appropriate document
   c) Click the OK button.

7. a) Click on an empty Commitment field below. The entire row becomes highlighted.
   b) Click on the LOV button located directly above the Commitment field
   c) Select the commitment type.
   d) Click on the OK button

8. a) Next click on the LOV button located above the Status column
   b) Select the appropriate status.
   c) Click on the Status Date field to enter the current date.
   d) Due date can also be entered if desired. Comment field can be used to enter notes for each commitment.

9. Click the Save button to save the entry.

Entering responses to commitments

10. a) Select a commitment from the main screen
    b) Click on the Related Response button.
    c) This will take you to either the Document Response or the Laboratory Response (for methods validation commitments) screen. If any responses have been entered, they will be displayed, otherwise the Response section block will be blank.

11. Search for documents which are related to the commitment by clicking on the LOV button located to the left of the Comments field.

12. This will bring up the Response Document Selection Screen used to search for supplements or annual reports that might be responses to the commitment being processed. Select the appropriate search criteria. The Letter Date field is used to restrict search to documents submitted after that date. Click on the Search button.

13. The search results will appear under the Selection Result section.
    a) Click to select
    b) Click on the OK button to go back to the Response screen with the selected result.
    c) From the Response screen you can enter the comments for that specific document.

14. The Laboratory Response screen is used to enter responses to a methods validation commitment. The information to be entered is contained in the report submitted by the laboratory that performed the analysis.

15. Click on the Save button in the main screen to save the responses and comments.

Updating post-approval requests, commitments, and responses

16. From the main screen click on the Fulfillment Status field to change the status of the post-approval request. Valid values for the status field are Y or N. If all the commitments have been submitted and deemed adequate by the reviewer, then project managers are required to update the fulfillment status to Y and enter an appropriate date.

17. a) Update the Status field of the main screen by clicking on the LOV button above the field. Choose the appropriate status and click the OK button.
    b) Enter the current date in the Status Date field
    c) Enter the appropriate overall comments
    d) Then click Save. This will close out the commitment.

18. If you wish, to update commitments and add final comments to specific documents, follow steps 10-15 above.

ATTACHMENT B

Instructions for Printing PACT Reports From COMIS

1. Log in to COMIS

2. Select 10 - COMIS Main Menu

3. Select 5 – ANDA/MIS

4. Select 6 – General Reports Menu II

5. Select 8 – Post Approval Commitment

6. Select either option 1, 2, 3, or 4 for the type of PACT report to print. Note that since PMs can enter PACs as they are received, even before the ANDA is approved, there is an option to print PACT requests for approved and unapproved ANDAs.