OFFICE OF GENERIC DRUGS

Issuing and Tracking of Consults

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PURPOSE

! This MAPP outlines procedures for issuing and tracking consults in the Office of Generic Drugs (OGD).

BACKGROUND

- OGD sometimes receives data for review that is either outside the expertise of its staff or for which there is a need to ensure consistency with Office of Review Management (ORM) decisions. To reach a scientific and/or regulatory decision, OGD must send the information to another part of CDER for review. This is done through a consult request. Common examples of OGD issues that require a consult request include safety evaluations of inactive ingredients, some labeling reviews, some bioequivalence protocol reviews, and statistical reviews of bioequivalence studies. These requests must be recorded and tracked to prevent undue delay in the OGD review process.

POLICY

- All consults within OGD are forwarded and tracked by the OGD Consult Coordinator according to the system outlined in this MAPP.

RESPONSIBILTIES

- Director, Office of Generic Drugs (or designee):

  Designates a Consult Coordinator.

- OGD Consult Coordinator:

  Keeps record of all consults.

  Prepares a monthly status report of outstanding consults.

  Provides a copy of completed consult to the OGD requestor.

  Arranges courier pickup of outgoing consult requests (and incoming consults if requested by ORM).

- Project Managers(PMs) /Reviewer/Associate Director for Medical Affairs:

  Prepares the consult request form (FDA Form 3291) and forwards consult and necessary information with copies to the Consult Coordinator. A sample Form 3291 is included as Attachment A to this MAPP.

- OGD Division Director (or designee)/Associate Director for Medical Affairs:

  Contacts the Division Director (or other appropriate individual) of the ORM review component responsible for the review of the consult and requests action on any consult pending for longer than 30 days past the requested completion date. A written summary of this contact should be forwarded to the Consult Coordinator.

- Document Room Personnel:

  Enter data on all consults into the MIS.

  Maintain a written log of all consults.

  Place copies of all outgoing consult requests in the appropriate abbreviated new drug application.

PROCEDURES

! Outgoing Consult Requests

The Reviewer and/or PM prepare FDA Form 3291. Requestors should keep a copy of the consult request for their records. The requestor ensures that the purpose of the consult and requested action are clearly described on the consult form. The form should clearly indicate that the completed consult be returned to the attention of the OGD Consult Coordinator with copies of all applicable reviews, including secondary and tertiary reviews. Any information critical to the review should be included in the consult request. Requestors should make every effort to identify specific issues that need to be reviewed, and should try to avoid very general nonspecific review requests.

The PM or requestor takes the consult request package to the Consult Coordinator. The Coordinator forwards the consult for processing through the document room for delivery by the Center=s courier service.

Consults going to new drug review divisions (as opposed to other review components) are sent to the responsible division through the appropriate Office of Drug Evaluation (ODE). The consults are sent to the attention of the ODE=s Associate Director for Regulatory Affairs.

! Consult Responses

Completed consults are returned to the OGD Consult Coordinator. The coordinator ensures that there are sufficient copies of the consult review and provides them to the PM or reviewer/requestor. Copies of the completed consults are forwarded by the coordinator to the document room for processing. The PM or reviewer/requestor processes the information provided in the completed consult according to appropriate review/action procedures.

! OGD Consult Priority Determination

Priority for completion is based on the application's review status, regulatory requirements, and issues related to the safety and efficacy of INDs and marketed drug products.

Highest Priority – 15 days:	INDs and ANDAs with possible serious safety concerns
High Priority – 30 days:	Applications close to approval (review disciplines are complete or near completion) and supplements with minor amendments
Medium Priority – 60 days:	Supplemental applications that are currently under review

	and will not be approved before 2 months
Low Priority – 90 days:	Documents that are not related to original ANDAs or supplements, or requests for ANDAs that will not be approved before 3 months

! Overdue Consults

OGD staff should contact the OGD Consult Coordinator to determine the status of consults.

If a consult is overdue by 30 days, the OGD Division Director or a designee in the division issuing the consult is informed. That Division Director contacts the director of the review component to request completion of the consult.

If the consult is overdue by 60 days, the Director of OGD or designee is informed and contacts the appropriate director or responsible individual.

! Monthly Report

The Consult Coordinator prepares a monthly report for OGD. It is distributed to the Director, Deputy Director, Division Directors, Approvals Manager and other project management staff.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

REQUEST FOR CONSULTATION

TO *(Division/Office)*:			FROM:	
DATE	IND NO.	NDA NO.	TYPE OF DOCUMENT	DATE OF DOCUMENT
NAME OF DRUG	PRIORITY CONSIDERATION		CLASSIFICATION OF DRUG	DESIRED COMPLETION DATE
NAME OF FIRM:				

REASON FOR REQUEST

I. GENERAL

- ☐ NEW PROTOCOL
- ☐ PROGRESS REPORT
- ☐ NEW CORRESPONDENCE
- ☐ DRUG ADVERTISING
- ☐ ADVERSE REACTION REPORT
- ☐ MANUFACTURING CHANGE/ADDITION
- ☐ MEETING PLANNED BY
- ☐ PRE--NDA MEETING
- ☐ END OF PHASE II MEETING
- ☐ RESUBMISSION
- ☐ SAFETY/EFFICACY
- ☐ PAPER NDA
- ☐ CONTROL SUPPLEMENT
- ☐ RESPONSE TO DEFICIENCY LETTER
- ☐ FINAL PRINTED LABELING
- ☐ LABELING REVISION
- ☐ ORIGINAL NEW CORRESPONDENCE
- ☐ FORMULATIVE REVIEW
- ☐ OTHER *(SPECIFY BELOW)*:

II. BIOMETRICS

STATISTICAL EVALUATION BRANCH	STATISTICAL APPLICATION BRANCH
☐ TYPE A OR B NDA REVIEW ☐ END OF PHASE II MEETING ☐ CONTROLLED STUDIES ☐ PROTOCOL REVIEW ☐ OTHER (SPECIFY BELOW):	☐ CHEMISTRY REVIEW ☐ PHARMACOLOGY ☐ BIOPHARMACEUTICS ☐ OTHER (SPECIFY BELOW):

III. BIOPHARMACEUTICS

- ☐ DISSOLUTION
- ☐ BIOAVAILABILTY STUDIES
- ☐ PHASE IV STUDIES
- ☐ DEFICIENCY LETTER RESPONSE
- ☐ PROTOCOL-BIOPHARMACEUTICS
- ☐ IN-VIVO WAIVER REQUEST

IV. DRUG EXPERIENCE

- ☐ PHASE IV SURVEILLANCE/EPIDEMIOLOGY PROTOCOL
- ☐ DRUG USE e.g. POPULATION EXPOSURE, ASSOCIATED DIAGNOSES
- ☐ CASE REPORTS OF SPECIFIC REACTIONS (List below)
- ☐ COMPARATIVE RISK ASSESSMENT ON GENERIC DRUG GROUP
- ☐ REVIEW OF MARKETING EXPERIENCE, DRUG USE AND SAFETY
- ☐ SUMMARY OF ADVERSE EXPERIENCE
- ☐ POISON RISK ANALYSIS

V. SCIENTIFIC INVESTIGATIONS

☐ CLINICAL	☐ PRECLINICAL

COMMENTS/SPECIAL INSTRUCTIONS:	
SIGNATURE OF REQUESTER	METHOD OF DELIVERY (Check one) ☐ MAIL ☐ HAND
SIGNATURE OF RECEIVER	SIGNATURE OF DELIVERER