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**POLICY AND PROCEDURES**

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**Office of Generic Drugs**

**Responding to Industry Inquiries with respect to Abbreviated New Drug Applications in the Office of Generic Drugs**

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**PURPOSE**

This MAPP clarifies the general principles for handling inquiries with respect to abbreviated new drug applications (ANDAs) from the authorized representative for an applicant with an ANDA submission (the authorized inquirer) by Regulatory Project Management (RPM) staff in the Office of Generic Drugs (OGD).

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**BACKGROUND**

The Center for Drug Evaluation and Research (CDER) believes it is important to timely respond to industry inquiries. Historically, OGD staff responded to a range of informal, ad hoc inquiries from industry regarding the status of ANDAs. In order to systematically improve the predictability and timeliness of the ANDA review process, however, industry and FDA negotiated the Generic Drug User Fee Amendment (GDUFA). GDUFA was enacted by Congress and became effective as of October 1, 2012. Pursuant to GDUFA, OGD implemented certain agreed-upon premarket review efficiency enhancements, such as complete response letters, and also committed to achieve certain agreed-upon application and backlog metric goals. As OGD works to fulfill its GDUFA performance obligations, industry has an interest in clarity regarding the process for handling inquiries going forward.

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**POLICY**

OGD policy is to provide prompt and accurate responses to any appropriate email or telephone inquiry from the authorized inquirer while maintaining appropriate confidentiality for commercial

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interests. Generally, inquiries should be returned within 2 business days of receipt. Any RPM staff member who has received an inquiry should make arrangements to forward it to a colleague should the staff member anticipate an absence that might prevent her or him from responding to the authorized inquirer for more than 2 consecutive business days.

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## RESPONSIBILITIES

- The RPM staff (as opposed to reviewers, team leaders, discipline specific project managers, deputies, division directors, other OGD management or OGD immediate office staff) are responsible for communicating with the authorized inquirer about the status of the ANDAs they manage for all disciplines and all aspects of the applications.
  - Industry will designate a single individual and make all inquiries through that authorized inquirer.
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## PROCEDURES

In carrying out the policy, the following procedures should be used when responding to inquiries. Successful communication must take into account that the authorized inquirer may not fully understand the review process and may misinterpret the information that is provided. The goal of the following procedures is to *decrease* potential confusion and miscommunication when responding to inquiries.

- Reviewers, team leaders, discipline specific project managers, deputies, division directors, other OGD management or OGD immediate office staff should refer all inquiries from the authorized inquirer on the status of an ANDA or related submissions to the RPM for that ANDA.
- Should an unauthorized inquirer contact the RPM, the RPM should not disclose any information related to the ANDA. The RPM should make sure the unauthorized inquirer understands that status inquiries should only be made by the authorized inquirer.
- RPM should respond to inquiries within 2 business days, keeping in mind that the authorized inquirer has the responsibility to obtain information from FDA and are accountable to their management.
- RPMs should make sure the authorized inquirers understand that there are multiple levels of review related to an ANDA, and variable workload queues for each level of review and in each review discipline. Some authorized inquirers may not be aware of either the volume of review work or of unplanned yet high priority disruptions (e.g., drug shortages).
- RPM should try to understand the reasoning behind the status inquiry. The underlying principle identified by the authorized inquirer may reveal valuable information to aid FDA in providing a timely review to address a public health need (e.g., patent expiration date, drug shortage). If the justification does reveal previously unknown information, the RPM will communicate this to OGD management and the review team.

- RPMs should communicate clearly that reviewers neither approve nor disapprove ANDAs. In addition, the results of a review are subject to revision if additional technical issues arise. These concerns may result in the need for additional information and/or studies, or may result in a conclusion that the proposed formulation cannot be approved.
  - RPMs should not provide dates or time lines for when reviews will be completed, when letters will be issued, or when other actions will be taken. Because workload and competing priorities affect action times, time lines are especially difficult to predict and should not be provided.
  - A *team* of reviewers from multiple disciplines reviews and acts on any single ANDA. Any statement on the status of an ANDA should not imply that one discipline or aspect of the review is unduly delaying FDA action on the ANDA since review by all disciplines, including all relevant inspections (manufacturing, testing, packaging, bio clinical, etc.) and review of potential legal issues is required for a complete response, tentative approval, or approval.
  - To provide accurate information to an industry inquiry, RPMs may have to discuss technical issues with review staff or team leaders before responding. RPMs should refrain from sharing specific deficiencies about an ANDA. There are established processes for transmitting ANDA deficiencies to applicants (e.g., Complete Response Letters and Easily Correctable Deficiencies).
  - RPMs will document inquiries about the status of a specific ANDA in the Document Archiving, Reporting and Regulatory Tracking System RPMs will not document inquiries using tally sheets or emails, or by other ad hoc means. Inquiries that are disruptive to the review process should be reported to a supervisor and OGD management.
  - Should an authorized inquirer become rude, RPMs should maintain a professional demeanor and immediately notify their supervisor.
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**EFFECTIVE DATE**

This MAPP is effective upon date of publication.

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**CHANGE CONTROL TABLE**

Effective Date	Revision Number	Revisions