OFFICE OF GENERIC DRUGS

Responding to Telephone Inquiries in the Office of Generic Drugs

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PURPOSE

- This MAPP clarifies the general principles for handling telephone inquiries from regulated industry and the public and/or their representatives by project management staff in the Office of Generic Drugs (OGD).

BACKGROUND

- The Center for Drug Evaluation and Research (CDER) believes it is important to respond to industry and to public inquiries as soon as possible. CDER emphasizes this in its documents on external communication. Industry has an economic interest in monitoring the progress of abbreviated new drug applications (ANDAs) very closely. The amount and type of information provided to the public by staff in OGD has varied over time because of a number of factors. Current practice, in keeping with CDER operating principles, is to communicate as openly as possible while maintaining appropriate confidentiality.

POLICY

- OGD policy is to provide prompt and accurate responses to inquiries while maintaining appropriate confidentiality for commercial interests. Generally, telephone calls should be returned within 48 hours of receipt. Staff should make arrangements for forwarding voice mail messages if absences exceed 2 consecutive days.

RESPONSIBILITIES

- The project management staff (as opposed to reviewers, team leaders, or division directors) is responsible for communicating with industry and representatives regarding the status of reviews by all disciplines and all aspects of applications that they manage.

PROCEDURES

- In carrying out the policy, the following procedures should be used when responding to inquiries. Successful communication must take into account that the inquirer may not fully understand the review process and may misinterpret what is stated by phone. The procedures listed below should decrease potential confusion and miscommunication when responding to telephone inquiries.

- Project managers should respond to requests within 48 hours, keeping in mind that authorized representatives from firms have the responsibility to obtain information from the Agency and are accountable to their management. Therefore, these individuals must be provided with information in a timely manner.

- Project managers should communicate clearly that reviewers neither approve nor disapprove applications. Results of the ***initial*** review are recommendations. Recommendations may or may not be accepted after secondary and tertiary supervisory review and subsequent discussion.

- Project managers should provide best estimates of the likely review time (including primary, secondary, and tertiary reviews). Inquirers may not understand that there are queues for primary, secondary, and tertiary reviews. Some callers may not be aware of either the large volume of review work or of unplanned disruptions (e.g., drug shortages) that can significantly delay the completion of normal reviews. Project managers should attempt to make sure callers understand clearly that any time estimates we provide are approximate, at best, and subject to change.

- Because of the uncertainties associated with the review process, project managers should not provide specific dates for reviews, letters, or other actions. This could result in business decisions being made based on the communication. Because workload and competing priorities affect action times, only approximate time lines can be provided (e.g., "The letter may issue within X weeks").

- Reasons for review staff absences are considered private information. An inquirer can be told that a particular delay is related to an absence, but the reason for the absence should not be made public.

- A review ***team*** reviews and acts on any single application. A statement on the status of an application should not imply that one discipline or aspect of the review is unduly delaying action on an application since action by all disciplines is required for approval. It is acceptable to indicate what reviews are or are not completed.

- Project managers should note whether there are inordinate numbers of status calls about a specific ANDA from one or more representatives of the application holder. They should also note situations where the representative(s) call different individuals within OGD about the same application. This may be disruptive to the review process and should be reported to the supervisor and OGD management for possible intervention.

- To provide accurate information, project managers may need to discuss technical issues with review staff or team leaders before responding. Discussion with the applicant about specific deficiencies in an application should be limited. The processes (e.g., letters, facsimiles, teleconferences) for transmitting deficiencies to applicants should be the mechanism for communicating application deficiencies.

- In the very rare case when a caller is abusive, project managers should maintain a professional demeanor and notify their supervisor immediately.

EFFECTIVE DATE

This MAPP is effective upon date of publication.