FDA Guidance for Review Staff and Industry:
Good Review Management Principles for PDUFA Products
Eli Lilly and Company Comments

This response is organized as three sections including an Executive summary followed by General comments on the content and then very specific line by line comments and suggestions with rationale.

Executive Summary:

- Overall the document needs to be more specific. The use of general terms is discouraged. More detail with respect to timing and timelines will result in clear expectations on behalf of the applicant and FDA. Common terminology consistent with current expectations is suggested.
- Overall the document needs to define a more transparent process. Direct dialogue should be encouraged throughout the review process. The discussion on inclusion of amendments in the first review cycle does not allow the applicant to understand the review strategy and timeline. Clear, direct communication will allow both the applicant and FDA to be prepared with appropriate resources. The inclusion of consultants in the review process should be transparent to the applicant. Consultants with authority for final recommendations should be considered adjunct members of the review team and included in presubmission meetings.
- Timing and timelines need to be added to the document. It is common for last minute discussions to occur regarding label language, post-approval commitments and risk management plans. Definition of timing for review of label proposals would allow the applicant and FDA to prepare with adequate resources and schedule discussions upfront. If time for communication between the FDA and the applicant on potential post-approval commitments is not planned as part of a well managed review process, it can result in hasty commitments leading to poorly conceived studies that are not feasible to complete, or that are not capable of providing the desired information. Timing for the review of risk management plans also needs to be discussed in the document to avoid delays.
- More detail should be added on the following processes to facilitate good review management principles:
  1. Meetings and agreements – Clearly delineated expectations and recommendations will result in a more efficient review.
  2. Information transfer to review teams – If the review team is different from the team involved in the IND review and presubmission meeting discussions, a formal process for information transfer should take place to ensure issues are not re-discussed during the application review.
  3. Inspections – Facility inspections are part of the review process and as such should be included in good review management.
  4. Training – Appropriate training is paramount to the success of the initiative.
  5. Lessons learned/wrap-up – A successful process should include metrics beyond timelines. Initiation of a review wrap-up promotes learning and continuous improvement.

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General Comments:

1. We commend the Agency for striving to improve communication and transparency of the review with industry. In an effort to meet this goal, it is suggested that a high-level review timeline with key milestones be shared with the applicant at the beginning of the review process and updated as the timeline is revised. A standard review timeline indicating key review milestones could be included in the guidance. This would facilitate the partnership between the applicant and FDA during the application review by preparing for interactions and responses.
2. Overall, some sections of this document are difficult to interpret. It appears a repeating format is applied to all sections resulting in repetitive information within a section and throughout the document. It would help to edit the detail and focus the discussion.
3. The draft guidance is often not specific on timelines and often uses words such as "timely or as soon as possible". It would be preferable to be more specific, as suggested in the detail comments on line 682 and 1082.
4. The document does not explicitly encourage direct reviewer and applicant dialogue to clarify reviewers' questions during the review process. This could be incorporated in III.C Communication between FDA and applicant in the Overall Principles. GRMP should incorporate such exchanges for greater efficiency.
5. Draft guidance does not provide adequate coverage of the importance of having meetings that have clearly delineated, scientifically sound and consistent recommendations. Effective meetings can lead to more effective reviews and should be incorporated into the Overall Principles section of this document.
6. It is suggested that at a minimum amendments planned and agreed upon during the pre-NDA/BLA meeting as well as amendments in response to agency information request letters submitted during the review be included in the first review cycle. In order to minimize impact on agency resources, the IR letter could provide a date by which a response could be included in the review.
7. It is beneficial to assign the review team as early as possible in the development process. Therefore we recommend this assignment be made at the presubmission meeting. This provides consistency throughout the presubmission discussions and application review. If resources prohibit assigning the review team prior to submission, an information transfer process should be implemented to ensure consistency and acceptance of prior agreements.
8. Consultants are certainly useful during the review process. The decision-making authority between both internal and external consultants and the review division should be defined upfront for the applicant. The consultants should also be included in the presubmission meetings to assure full agency alignment on submission content. Consultants should be aware of and agree to the review timelines.
9. Good review management principles should include the pre-approval inspection process. Regular communication with the applicant should include the status of inspection requests. This is suggested in the Wrap-Up and Labeling

section of the document on line 1118, but not adequately incorporated into the body of the guidance. Specific comments are included on line 431.

10. Overall the document tends to suggest different process and language for CBER versus CDER regulated products. It would help the applicant to prepare and communicate if the same terminology and process were used. Also, the draft guidance does not encourage consistency across molecules and therapeutic areas.
11. The CTD format should be referenced.
12. The suggested time frames for applicant response may not be sufficient to allow for a preparation of a response. For example, preparation of a response to FDA after a 45 day meeting, but prior to a 60 day decision date. Communicating to the applicant as early as possible would facilitate the review.
13. The success of good review management relies on fully trained staff at FDA, especially the project management skills of the FDA RPM's. FDA training is thus critical and should be included in the background discussion and in section V. Implementation and Evaluation, on line 1413. It is recognized that reviewer training is an additional activity to GRMPs.
14. It is not uncommon for tradename changes to delay the launch of potentially life saving drugs. It is suggested that the tradename assessment process be done either at filing or ideally at the presubmission meeting and communicated to the applicant. This would avoid potential delay of distribution of product.
15. Often an applicant references drug master files in an NDA/BLA. During the initial filing period, the applicant should be notified by the Agency if the contents of a master file are known to be deficient. While the information in the master file is confidential and can not be shared with the applicant, it is not uncommon for an applicant to work with the sponsor of the drug master file to assure the deficiencies are corrected in a timely manner. Thus, if a master file is known to be deficient, this should be communicated to the applicant as soon as possible, even during a presubmission meeting, so corrective actions can be taken prior to filing.
16. At the end of a review cycle and action letter, it would be very useful for the FDA and the applicant to have a debrief of the whole application review process and a "Lessons Learned" meeting. The FDA could also issue a "report card" for both the FDA and the industry as a mechanism of tracking adherence to GRMPs.
17. It is acknowledged that some of the proposals may not be consistent with current MAPPS. Ideally good review practices would be consolidated into one MAPP and existing MAPPs could be edited to be consistent.

Sub-section (Line #)	Issue or Guidance Text	Suggested Text	Rationale and References
II Background			
Line 19	Guidance only for first cycle review	After sentence ending on line 21 suggest adding sentence "Similar principals laid out in the guidance document should also apply for subsequent cycle reviews."	This addition would encourage the applicant and the agency to continue the collaborative approach to review applications and ensure minimal change in review team constitution and ensure continuity. Although this is alluded to in "Cycles of review" (line 1384), it needs emphasis, especially continuity.
Line 22	Guidance is based on experience of CBER and CDER but lacks examples of best practices.	An appendix with illustrative examples of best practices of GRMP both within the agency and between the agency and industry would be useful.	These examples would allow some consistency.
Line 47	This guidance is expected to lead to greater consistency and efficiency of the review process within individual review divisions, across review divisions, and between CDER and CBER.	This guidance is expected to lead to greater consistency and efficiency within and across review divisions and to enhance the transparency of the review process between the review team and the applicant.	With a better understanding of the review process and schedule, the applicant can then better partner with the review team to meet the PDUFA goals.
Lines 57-67	The draft guidance document emphasizes PDUFA expectations and metrics.	The background info focuses on best practices for applicants (lines 57-67) but offers little in the way of expectations of Reviewer practices and offers nothing beyond PDUFA expectations and metrics.	This would allow the draft guidance to fulfill the intention proposed in lines 17-21
Line 63	"Dependent on the availability	..adequate resources are	The guidance should put forth an expectation

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	...."	required...	that the agency will ensure adequate resourcing especially since they will receive more lead time from the applicants as encouraged in the guidance. Such encouragement will allow PDUFA timelines to be met and ensure GRMPs.
III. Overall Principles A. FDA Focus			
Line 93	This sentence discusses only the issue of time	Suggest adding the concept of improved efficiency in this sentence both within the agency as well as between agency and applicant interactions.	The primary focus of GRMP's is to lead to greater efficiency of the review process, as noted on lines 47-49.
Line 113	The GRMPs emphasize the importance of (1) a strong interdependence among the primary FDA review team, (2) frequent interactions between the primary review team and supervisory reviewers, and (3) the critical role of effective project management in the successful completion of the first-cycle review.	The GRMPs emphasize the importance of (1) a strong interdependence among the primary FDA review team, (2) development and communication of key milestones of the review timeline to the applicant, (3) continuous interactions between the primary review team and supervisory reviewers, and (4) the critical role of effective project management in the successful completion of the first-cycle review.	A fourth aspect to a successful review is the development and communication to the applicant of key milestones in the review timeline. Again, if the applicant understands the agency's key milestones of the review timeline, the applicant can partner with the review team to meet the PDUFA goals. The interactions between the primary and supervisory reviewers should be ongoing to allow sufficient time to identify and investigate potential issues with the application and come to consensus on resolution.
III. Overall Principles B. Applicant Focus			

Sub-section (Line #)	Issue or Guidance Text	Suggested Text	Rationale and References
Line 146	..leads to submission of a complete application, with the exception of safety updates, for FDA review.	…leads to submission of a complete application, with the exception of safety and stability updates, for FDA review.	Additional stability data should be provided during the review process to allow an adequate assessment of product integrity.
Line 153	The FDA retains the authority to decide whether to review application amendments, solicited or unsolicited , submitted during the first review cycle.	The FDA retains the authority to decide whether to review application amendments, solicited or unsolicited, submitted during the first review cycle, with the exception of those planned and agreed to in previous discussions with the applicant. In information request letters, FDA will notify the applicant under what circumstances, for example response timing, the amendment will not be reviewed during the first review cycle.	The FDA should review planned amendments minuted in presubmission discussions. The applicant should clearly understand if solicited or unsolicited amendments will not be included in the first review cycle prior to submitting the amendment. This information will assist the applicant in prioritizing the response to facilitate the overall submission review and approval.
Line 157	"Competing workload priorities…"	It is the expectation of the applicant that the agency provides adequate resourcing.	Such caveats may allow the agency to not meet PDUFA timelines.
III. Overall Principles C. Communication between FDA and Applicant			
Line 165	Missing other time points of communication between FDA and applicant	Suggest adding 45 day presentation ,74 day communication as well as face to face 90 day meeting.	Comprehensive discussion of possible times of communication between FDA and applicant. Could also add encouragement for both written and verbal responses to presubmission meeting discussion topics. For some issues written

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			responses by FDA will suffice, while other topics require discussion between the applicant and FDA. This strategy, while sometimes used, is not encouraged in current guidance. It would promote more efficient sharing of information.
IV. Process Principles			
Line 187	A. Presubmission	A. Development Activities	The term Presubmission is confusing as it can be interpreted as the review process when information is presubmitted as defined in 21 CFR 314.50(d.1.iv.) This is normally referred to as Development in other guidance documents.
Line 209	Missing emphasis on meetings prior to EOP2.	Suggest adding discussion on pre-IND, IND and EOP1 meetings.	Comprehensive discussion of possible times of communication between FDA and applicant.
Line 217	Meetings during the IND phase and SPA submissions are invaluable opportunities for the review division and the applicant to review....	Meetings during the IND phase and SPA submissions are invaluable opportunities for the review division, any consultants and the applicant to review....	It is beneficial to include consultants in meetings for general agreement and consistency, especially in the presubmission meetings.
Line 227-228	The pre-NDA/BLA meeting generally should be schedule 6 to 12 month prior to the anticipated date for applications submission.	The pre-NDA/BLA meeting generally should be schedule 6 to 12 month prior to the anticipated date for applications submission. Use of FDA consultants should be identified and included in the pre-NDA/BLA meeting preparation.	Consultants should be included in the presubmission meetings.

Sub-section (Line #)	Issue or Guidance Text	Suggested Text	Rationale and References
Line 233	...preparing for the pre-NDA/BLA meeting, the review division should attempt to address...	... preparing for the pre-NDA/BLA meeting, the review division should address....	The review division should be able to address specific questions in the pre-NDA/BLA meeting.
Line 276	Background package	Suggest replacing this with briefing document.	Use of standard terminology.
Line 279	...comprehensive summary of all relevant data...	Suggest replacing "comprehensive" with "focused".	It may not be possible to be concise (Line 276) and comprehensive, but it would be possible to be concise and focused.
Line 294	Risk management plan	Suggest adding reference to guidance in footer.	
A. Presubmission 3. Communication between FDA and Applicant			
Line 317	Concept of clear and timely communication	Suggest adding more specific timing and/or having a continuous dialogue with the applicant.	This suggestion is in the spirit of the GRMP guidance put forth in the background section.
Line 329	FDA recommends following their recommendations in their entirety.	Suggest rewording to bring forth a spirit of mutual learning.	This suggestion is because both the FDA and applicant are learning from the drug development activity.
B. Application Receipt Process (Prefiling)			
Line 341	Review team roles and responsibilities are clarified during this process.	Review team, supervisory team, consultant and signatory roles are clarified during this process.	It is Industry experience that in addition to the review team roles, the supervisory team, consultants and signatory roles need clarification.
Line 366	..conduct an administrative review, including ensuring that financial disclosure information	..conduct an administrative review.	It is not clear why financial disclosure information is singled out as an item of concern. Remove or provide a complete list,

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	has been provided by the applicant.		including DMF acceptability. It may be helpful to clarify that other review team members will participate in the review.
Line 379	The primary review team should be assigned as soon as possible after receipt of a new application.	The primary review team should be assigned prior to the presubmission meeting. If new team members are assigned, previous commitments should be honored as part of a formal information transfer process.	This revision should be moved with the presubmission discussions in the paragraph starting on line 223.
Line 387		Insert: If multiple FDA review Divisions and /or Centers are included in the review of an application (i.e. combination products), FDA should determine which center or division will have ultimate review authority for each portion of the submission and thus be assigned responsibility to review and summarize deficiencies into DR letters.	The review of a section of the application should be limited to review by the Center/Division with the review authority. Multiple reviewers of the same data set are not an efficient review process.
Line 400	• Environmental assessment	• Environmental assessment • Microbiology • Virology • Office of Compliance • Additional Centers	The bulleted list should be complete and represent all parties that may be involved as consultants. It would be beneficial to include the consultants in the presubmission meetings and the pre-filing assessments discussed on lines 217.

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Line 420		Suggest discussing consultations such as OPSS and with other divisions such as DCRDP for QT issues.	Comprehensive discussion on how to manage consultations within the agency
Line 421	Consultants	Suggest allowing applicants to suggest names of possible external consultants to the agency at the pre-NDA meeting.	This will allow choice of consultants who may be familiar with the data and therefore increase the efficiency of the review process
Line 428		Add: The RPM should track the status of inspections and communicate with the applicant regarding the decision to inspect and the timing.	The status or completion of an inspection can impact the review cycle. The review team should communicate clearly and effectively with those parties involved in inspections.
Line 442	Designation of priority review	Suggest encouraging this determination at the pre-NDA meeting.	This will again allow for efficiency of the process since it will dictate the initial filing meeting timelines and preparation on the part of the reviewers would be easier.
Line 464	Once the decision is made to assign a priority review, that designation should not be changed during the first review cycle, regardless of findings during the review.	Once the decision is made to assign a priority review, that designation cannot change.	Better clarity is needed on the designation of a priority review during the review cycle. The decision of a priority review only impacts the initial review clock. The review times for subsequent amendments are the same regardless of review status.
Lines 498-600	Substantive deficiencies in applications	Suggest adding an appendix with the most common deficiencies that CDER and CBER have noted in their past reviews.	Allows for better understanding of the possible flaws and applicants can then avoid these flaws in their applications resulting in greater efficiency.
Line 517		Add: Prior to the filing of the	This practice is used by some, but not all

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		application, near day 45, the FDA and the applicant should schedule the NDA/BLA Presentation meeting. During this meeting, the applicant presents a summary of the application to the FDA review team and responds to their specific questions. This open dialogue promotes a clear understanding of the key findings and content of the application and may identify and/or resolve possible deficiencies.	review offices. It is very helpful for both the Applicant and the Review team as it affords the opportunity for clear communication regarding the application and clarification of potential filing issues.
Line 526-7	Communication between applicant and sponsor	Suggest allowing communication for clarifying questions, regarding input from consultations, etc	This transparency on the FDA's part will allow applicants to inquire less frequently of the outcome of the consultations and therefore increase efficiency
Line 538	We encourage communication with the applicant…	We encourage communication between the applicant and FDA…	
Line 552	…required information and format…	…required information…	The CFR currently does not specify CTD format. The guidance should reflect current expectations.
Line 601	Advisory committee meeting	Guidance should encourage the agency to communicate this decision to the applicant at the time this decision is made (filing	This will allow the applicant to prepare for the advisory meeting and will reduce redundancy of the presentations since the applicant can share their presentations with the agency in

Sub-section (Line #)	Issue or Guidance Text	Suggested Text	Rationale and References
		meeting).	time.
Line 615	If the deficiencies appear to be readily correctable, the division should promptly notify the applicant of the deficiencies and establish a date by which the applicant must satisfactorily respond to avoid a refuse-to-file decision. If the reviewers believe that the deficiencies...	The division should promptly notify the applicant of the deficiencies and establish a date by which the applicant must satisfactorily respond to avoid a refuse-to-file decision. If the reviewers , after consulting with the applicant, believe that the deficiencies...	The applicant and the review team should together define those issues that are readily correctable. It may appear that an issue is significant to the review team, when the applicant is actually capable of quickly resolving the deficiency.
Line 618	If the reviewers believe that the deficiencies are not readily correctable by the applicant, or if the applicant fails to respond satisfactorily to notification of refuse-to-file issues, the specific refuse-to-file deficiencies should be conveyed to the applicant in a letter signed by the review division director (see next sections).	If the reviewers believe that the deficiencies are not readily correctable by the applicant, the division should discuss the issues with the applicant prior to making a final determination. If the reviewers conclude that the deficiencies are not readily correctable or the applicant fails to respond satisfactorily to notification of refuse-to-file issues, the specific refuse-to-file deficiencies should be conveyed to the applicant in a letter signed by the review division director (see next sections).	FDA should not independently determine that a given deficiency is not readily correctable, without first discussing the issue with the applicant and learning the timing for correction of the deficiencies.
Line 625		Responses to information requests prior to filing are considered part of the initial	This statement should be added to the guidance to clarify that the initial application as filed, including any amendments solicited during the

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		submission and should be reviewed during the initial review cycle.	filing assessment, is complete and not considered amended and hence is reviewable during the first cycle.
Line 649	The applicant should be aware that amendments containing responses to filing review issues identified by the FDA and communicated according to the PDUFA goals may or may not be reviewed by the FDA during the first review cycle.	The applicant should be aware that amendments containing responses to filing review issues identified by the FDA and communicated according to the PDUFA goals may or may not be reviewed by the FDA during the first review cycle. FDA will notify the applicant of this decision in the information request letter.	In the spirit of transparency, in the IR letter FDA should indicate to the applicant whether a complete response will be included in the first review cycle. It may be appropriate for FDA to specify a date by which a complete response will be included in the first review cycle. This information will assist the applicant in appropriately prioritizing its response.
Line 682	"early in the review cycle"	Suggest adding a definition of "early".	Clarify timelines.
Line 701	FDA planning	Suggest incorporating the following activities in this planning process: determining additional resource needs; planning meetings with applicant to give status reports and answer questions.	This will allow for more efficient system and sponsors will inquire less frequently.
Line 720	The applicant should not expect to be apprised of all interim timelines for internal FDA processes, but will be involved by the FDA in planning activities that clearly require	The applicant should not expect to be apprised of all interim timelines for internal FDA processes, but will be involved by the FDA in planning activities that clearly require	It is extremely helpful to the applicant to be apprised of any FDA activities that require input or a response from the applicant. The applicant can more effectively organize resources if aware of the review schedule. Unnecessary request for status from the

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	applicant input, such as an advisory committee meeting.	applicant input, such as an advisory committee meeting, information requests, discipline review letters and inspections. An overall high-level timeline should be supplied to the applicant including the previously mentioned milestones and any changes to the timeline should be communicated.	applicant may be avoided and a better partnership between FDA and the applicant can be achieved throughout the review cycle.
Line 740	Any changes to the planned timeline for the review should be communicated among the entire review team and discussed with the signatory authority for the application.	Any changes to the planned timeline for the review should be communicated among the entire review team and discussed with the signatory authority for the application. The applicant should be notified.	Changes to the timeline should be communicated to the applicant to facilitate resource planning.
Line 772 and 813	Written opinion of secondary reviewer	Written opinion of secondary reviewer should be required, even if this is a simple concurrence with the primary reviewer.	This will provide additional clarity of process.
Line 874	In such cases, it is generally most efficient to include any substantive deficiencies identified by the discipline review in the action letter for the application.	Substantive deficiencies should be communicated to the applicant regardless of the PDUFA goal date.	If possible, substantive deficiencies should not be withheld from the applicant as this will ultimately delay the review and approval. This philosophy is also discussed on line 1339.
Line 881	Consideration should be given to	Consideration should be given to	The applicant should be involved in the

Sub-section (Line #)	Issue or Guidance Text	Suggested Text	Rationale and References
	the seriousness of the identified deficiencies and the expected time required for the applicant to respond satisfactorily, knowledge of any other serious deficiencies that might prevent approval of the application on the first cycle, competing division workload priorities, and division resource allocation.	the seriousness of the identified deficiencies and timing of the response. The expected time required for the applicant to respond satisfactorily should be discussed directly with the applicant. Also knowledge of any other serious deficiencies that might prevent approval of the application on the first cycle, competing division workload priorities, and division resource allocation should be considered and discussed.	discussions to facilitate the decision making process based on the information known only by the applicant.
Line 887		Add: The review division will review all information as agreed to in presubmission meetings. The review division should clearly communicate the review plan and timing with the applicant.	It is important that the applicant know the review plans. Changes in the agreements or review schedule must be communicated to the applicant.
Line 912	Major amendments	Identifying the parameters of a major amendment would clarify expectations for the applicant.	
Line 961	F. Advisory Committee Meetings	The guidance should encourage sharing of slides with an opportunity for open discussion of issues. This would minimize discussion between FDA and the	

Sub-section (Line #)	Issue or Guidance Text	Suggested Text	Rationale and References
		applicant and allow the meeting to stay focused on the feedback from the committee. The FDA should request the applicant's feedback on issues raised by the advisory committee.	
Lines 1082	...the review division as far in advance of the meeting as feasible to facilitate meeting...	Define "advance" with specific time; example 1 month.	This will add clarity of process and expectations.
Line 1086	generally will share its presentation with the applicant in advance of the AC meeting.	Define advance with specific time; example 1 month.	This will add clarity of process and expectations.
Line 1086	generally will share its presentation with the applicant in advance of the AC meeting.	Remove word "generally".	It should be standard practice to share presentations for AC meetings.
Line 1124	...used to identify the requisite parameters for the subsequent labeling negotiation.	The requisite parameters should be defined and clarified.	
Line 1130-31	The planning process should also anticipate communication events with the applicant for labeling negotiation.	These communication events should be defined and clarified.	
G. Wrap-Up Meeting			
Line 1131-33	Early label negotiation	Suggest adding phrase – CMA should allow for early label negotiations.	
Line 1142-43	Early communication of potential labeling issues...	Early communication, at least two weeks prior to the action	General terms, such as early, need clear definition to allow the applicant and FDA a

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		date, of issues with labels, post approval commitments, risk management plans or any other labeling...	clear understanding of the expectations.
Line 1171		Add: Web conferencing or direct discussion of labeling is encouraged to minimize the delays associated with faxing proposals back and forth.	A practice commonly used is to fax proposed language and counter-proposals back and forth between FDA and the applicant. Direct discussion and resolution through means such as online conferencing would be more efficient.
Line 1179	(21 USC 352)	No edit suggested.	Define this acronym in Appendix A.
H. Action			
Line 1309	...and a copy sent to the applicant by facsimile.	...and a copy sent to the applicant by facsimile, or scanned and sent through secure email.	Secure email should be an acceptable means of communication when possible.
Line 1321	...It should be reasonably clear to the applicant whether the application may be headed toward approval or whether another review cycle will be needed to address the Agency's concerns.	...It should be clearly communicated to the applicant whether the application is be headed toward approval or whether another review cycle will be needed to address the Agency's concerns.	Good communication is an important part of the review process and the applicant should not need to assume approval will or will not occur.
Line 1372	...approval, nonapproval, complete response).	...approval, complete response).	The terminology is inconsistent with that used on line 1205.