SOPP 8413 Appendix B: Review Committee Member Considerations for 506B Annual Reports

The following information in the 506B Annual Report should be reviewed.

#	Information	Information submitted in the 506B Annual Report
1.	**Applicant Name**	Applicant's Name as found on FDA Form 356h
2.	**Product Name (trademark and generic, as applicable)**	Product name, and any trademark or /proprietary/generic name(s)
3.	**BLA/STN # or NDA #**	STN or NDA ######
4.	**Date of original U.S. approval of BLA or NDA:**	Date BLA or NDA was originally approved in the U.S.
5.	**Postmarketing requirement or commitment Number**	Number from the approval letter or other letter establishing a PMR or PMC
6.	**Submission number corresponding to the letter establishing a PMR or PMC**	Submission number resulting in the establishment of the PMR or PMC, example, STN 123456/78
7.	**Date postmarketing study requirement or commitment was issued**	Date of the letter establishing the PMR or PMC
8.	**Description of postmarketing study requirement or commitment**	Description of the PMR or PMC from the letter establishing the PMR or PMC
9.	**Original milestone schedule**	Original milestone schedule from the letter establishing the PMR or PMC, for example • Final study protocol: original date • Patient accrual completion: original date • Study completion: original date • Final study report: original date
10.	**Revised milestone schedule, if appropriate**	Revised milestone schedule, if supplied by the applicant, for example • Final study protocol: updated date • Patient accrual completion: updated date • Study completion: updated date • Final study report: updated date
11.	**Current status of the requirement or commitment**	Current status of PMR or PMC. Status should be: Pending, Ongoing, Delayed, Terminated, or Submitted

#	Information	Information submitted in the 506B Annual Report
12.	**Explanation of Status for the study or clinical trial (This should entail a brief explanation about how the study is progressing in reference to the original projected schedule)**	For each study, does the status explanation include: a. The status of the study and any difficulties encountered in completing the study. b. For each clinical trial, does the status explanation include: 1. The status of the trial 2. Whether enrollment has started 3. Any difficulties encountered in completing the trial 4. The number of participants enrolled 5. The expected completion date of the trial 6. Registration information into ClinicalTrails.gov [section 402(j) to the Public Health Services Act (42 USC § 282(j))]