APPENDIX B. PMR/PMC DEVELOPMENT GUIDE

This guide may be used by the reviewers when developing a PMR/PMC.

1. If required by regulation, characterize the review issue leading to a **PMR**. ***If not a PMR, skip to 2***.

   - What is the regulatory basis for requiring the study/clinical trial, i.e., which regulation does it fall under?

     ☐ Accelerated approval (21CFR 314.510/Subpart H and 601.41/Subpart E)
     ☐ Animal efficacy confirmatory studies (21 CFR 314.610 and 601.91(b)(1))
     ☐ Pediatric requirement (21 CFR 314.55(b) and 601.27(b))
     ☐ FDAAA required safety study/clinical trial (Section 901)

   - What is the PMR intended to assess or identify?

     ☐ Assess a known serious risk related to the use of the drug
     ☐ Assess signals of serious risk related to the use of the drug
     ☐ Identify an unexpected serious risk when available data indicate the potential for a serious risk

   - How will the safety issue be addressed by the PMR? By conducting:

     ☐ An analysis of spontaneous postmarketing adverse events
     Do not select this if: such an analysis will not be sufficient to assess or identify a serious risk

     ☐ An analysis using pharmacovigilance system
     Do not select this if: the new pharmacovigilance system that FDA is required to establish under section 505(k)(3) has not yet been established and is thus not sufficient to assess this known serious risk.

     ☐ A study (all other investigations, such as investigations in humans that are not clinical trials as defined below (e.g. observational epidemiologic studies), animal studies, and laboratory experiments
     Do not select this if: a study will not be sufficient to identify or assess a serious risk

     ☐ A clinical trial: any prospective investigation in which the applicant or investigator determines the method of assigning treatment or other interventions to one or more human subjects

   - What type of study or clinical trial is required?

     ☐ Pharmacoepidemiologic study (list risk to be evaluated)
     ☐ Registry studies (not part of a REMS)
     ☐ Primary safety study or clinical trial (list risk to be evaluated)
     ☐ Subpopulation (list type)
     ☐ Thorough Q-T clinical trial
     ☐ Nonclinical safety study (e.g., carcinogenicity, reproductive toxicology)
     ☐ Non-clinical study (laboratory resistance, receptor affinity)

☐ Pharmacokinetic studies or clinical trials
☐ Drug interaction or bioavailability studies or clinical trials
☐ Dosing studies
☐ Additional data/analysis requested for a previously submitted/expected study (Provide explanation)
☐ Meta-analysis of previous studies/clinical trials
☐ Other (Provide explanation)

2. If not required by regulation, characterize the review issue leading to this **PMC**

☐ Quality study without a safety endpoint (e.g., manufacturing, stability)
☐ Pharmacoepidemiologic study not related to safe drug use (e.g., natural history of disease; background rates of AEs)
☐ Clinical trials primarily designed to further define efficacy (e.g. in another condition, different disease severity, or subgroup)
☐ Dose-response study performed for effectiveness
☐ Nonclinical study, not safety-related (specify)
☐ Other

Note: Please document clearly and concisely the technical rationale for requiring or recommending a PMR/PMC in your review documentation.