SOPP 8101.1 Appendix 3 PREA Compliance Checklist

Product:_____
_____

Sponsor: _____

Clinical Reviewer: _____

Date:_____

Initial document reviewed/ discussion of PREA Date

Pre IND/IDE _____
New IND/IDE_____
Meeting _____
BLA/NDA submission _____

Orphan Drug Status:

Yes (PREA waiver granted- Date**)** _____
No (Continue with PREA compliance**)** _____

Agreement to Comply with Pediatric Assessments:

Yes **No** (skip to next bolded comment regarding Written Request))

If **yes**, when? _____

How documented? _____

If no, the date of Sponsor's Written Request or FDA-granted waiver:
_____

Nature of Request:

Full Waiver _____
Partial Waiver _____
Deferral _____

Proposed Justification for the Request (indicate sponsor or FDA review**)**:

Orphan drug status granted _____
Disease or condition does not exist in children _____
Not a meaningful health benefit/Inadequate use _____
Studies are impossible/impractical _____
Product is unsafe/ ineffective_____
Failed efforts to develop a formulation _____

PREA reviewer Consult obtained (Y/N)?_____

Request granted **Yes/No** **Date**:

Full waiver _____
Partial Waiver_____
Deferral_____