PEDIATRIC DEVELOPMENT OF THE DRUG OR BIOLOGICAL PRODUCT

Under the Food and Drug Administration Safety and Innovation Act (FDASIA), a sponsor who will be submitting an application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration is required to submit an initial Pediatric Study Plan (PSP) within 60 calendar days after the date of the end-of-Phase 2 meeting or such other time as may be agreed upon between the Secretary and the applicant (21 USC 355c(a) and (e)).

The initial PSP must include an outline of the pediatric study or studies that the applicant plans to conduct (including, to the extent practicable, study objectives and design, age groups, relevant endpoints, and statistical approach); any request for a deferral, partial waiver, or waiver, if applicable, along with any supporting documentation (21 USC 355c(e)(2)(B)). For questions regarding the completion of the initial PSP, contact the appropriate review division Regulatory Project Manager.

An example of how an initial PSP can be organized is included below:

1. OVERVIEW OF THE DISEASE IN THE PEDIATRIC POPULATION (1-3 pages)

2. OVERVIEW OF THE DRUG OR BIOLOGICAL PRODUCT (1-3 pages)

3. OVERVIEW OF PLANNED EXTRAPOLATION TO SPECIFIC PEDIATRIC POPULATIONS (1-3 pages)

Information on extrapolation may be found in section IV. C. of the Guidance for Industry: How to Comply with the Pediatric Research Equity Act.
http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM077855.pdf

4. PLANNED REQUEST FOR DRUG- SPECIFIC WAIVER(S) (1-3 pages)

Information on waiver requests may be found in section VI of the Guidance for Industry: How to Comply with the Pediatric Research Equity Act.
http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM077855.pdf

5. PLAN TO REQUEST DEFERRAL OF PEDIATRIC STUDIES (1-2 pages)

Information on deferral requests may be found in section VI of the Guidance for Industry: How to Comply with the Pediatric Research Equity Act.
http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM077855.pdf

***6.* TABULAR SUMMARY OF PLANNED NONCLINICAL AND CLINICAL STUDIES**

7. AGE-APPROPRIATE FORMULATION DEVELOPMENT (1-3 pages)

Information on formulation development may be found in section V. C. of the Guidance for Industry: How to Comply with the Pediatric Research Equity Act.

http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM077855.pdf

8. NONCLINICAL STUDIES (1-3 pages)

9. CLINICAL DATA TO SUPPORT DESIGN AND/OR INITIATION OF STUDIES IN CHILDREN (1-5 pages)

10. PLANNED PEDIATRIC CLINICAL STUDIES

10.1 Pediatric Pharmacokinetic studies (1-10 pages)
10.2 Clinical Effectiveness and Safety Studies Planned (1-10 pages)

11. TIMELINE OF THE PEDIATRIC DEVELOPMENT PLAN (1 page)

12. AGREEMENTS FOR PEDIATRIC STUDIES WITH OTHER REGULATORY AUTHORITIES (1-3 pages)

If there is a pending or agreed pediatric investigational plan with EMA, sponsors should provide the corresponding application number (e.g., EMEA-000206-PIP01-08).