

Skyla

(levonorgestrel-releasing intrauterine system)

**Full Safety and Drug Utilization Review Provided
in Background Materials**

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Skyla – Pediatric Postmarket Review

- **Skyla was first approved January 9, 2013 for use in adolescents and adults, which prompted this mandated pediatric postmarket review.**
- **Skyla is indicated for prevention of pregnancy for up to 3 years.**
- **Skyla is a small intrauterine system, T-shaped polyethylene frame with a steroid reservoir containing 13.5 mg levonorgestrel.**

Pediatric Postmarket Safety and Use Review

16 unique cases with SAEs, no deaths, 4/4/2013 through 8/31/2015

✓ **Types of SAEs (cases may include 1 or more SAEs)**

- **11 intrauterine system expulsion***
- **4 altered bleeding (irregular spotting, frequent or heavy bleeding)**
- **2 pregnancy**
- **1 pelvic inflammatory disease**

Of all users, the proportion who were pediatric patients aged 0-17 years with a prescription and/or procedure claim for Skyla was 6% (1,583 out of 26,915 total patients) from 8/2013 - 7/2015.**

*** 1 expulsion had altered bleeding, 1 expulsion with pregnancy**

****Data source: SHS Integrated Dataverse (IDV™), extracted Dec 2015 (Data obtained from a sample of 131 pharmacies, 3,258 clinics, hospitals and physician offices)**

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FDA will continue its standard ongoing safety monitoring.

Does the Committee concur?