

**Background Document for Joint Meeting of Advisory
Committee for Reproductive Health Drugs and the Drug
Safety and Risk Management Advisory Committee**

December 8, 2011

NDA 21-098 Yasmin

(3 mg drospirenone/0.03 mg ethinyl estradiol)

NDA 21-676 YAZ

(3 mg drospirenone/0.02 mg ethinyl estradiol)

NDA 22-532 Beyaz

**(3 mg drospirenone/0.02 mg ethinyl estradiol/0.451 mg levomefolate
calcium)**

NDA 22-574 Safyral

**(3 mg drospirenone/0.03 mg ethinyl estradiol/0.451 mg levomefolate
calcium)**

Bayer HealthCare Pharmaceuticals, Inc.

Primary Indication:

Prevention of Pregnancy

Dosing regimen:

Oral tablet taken once daily

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Food and Drug Administration

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