

## **Answers to Frequently Asked Questions: OTC Plan B<sup>®</sup>**

Updated November 7, 2006

*In August of 2006, the U.S. Food and Drug Administration (FDA) approved Plan B<sup>®</sup>, an oral emergency contraceptive, for sale in pharmacies without a prescription to persons who were 18 years of age or older. This FDA approval is based upon the manufacturer's new packaging, age limitation and compliance monitoring effort. Pharmacies began receiving the newly labeled packages for sale without a prescription during the first week in November.*

### **Where will OTC Plan B<sup>®</sup> be available to consumers?**

Plan B<sup>®</sup> will be available only at licensed pharmacies and other licensed health care facilities. The medication will be kept behind the pharmacy counter and may be sold without a prescription to customers 18 years of age or older. It may be dispensed pursuant to a prescription to persons under 18 years of age.

Proof of age may be demonstrated by a person providing a valid government issued identification showing the person is at least 18. A photo ID is not required.

A pharmacist must be on duty for the product to be sold. Actually, a pharmacist is required to be on duty for the pharmacy to be open. However, a pharmacist is not required to make the transaction.

Plan B<sup>®</sup> will not be available in convenience stores or other locations where OTC drugs are sold without a pharmacist on duty. It will be available only in a licensed pharmacy or health care facility.

### **How will Plan B<sup>®</sup> be distributed to pharmacies?**

Plan B<sup>®</sup> will be distributed to wholesalers for shipping to licensed pharmacies and other licensed health care clinics. The new Plan B<sup>®</sup> packaging will provide a "dual label" Rx/OTC product. The current Rx package will be replaced by the dual label product package that can be used as both the prescription and the OTC product.

The new package will contain an OTC drug facts section and will also contain a consumer product information insert. The new product will state "Rx only for age 17 and younger" on the main panel. The back of the package will have an area in which an Rx label can be affixed.

The new package and accompanying information can be found on the FDA website at: <http://www.fda.gov/cder/foi/label/2006/021045s011bl.pdf> .

**Are there special counseling requirements for the OTC product?**

No. There are no special counseling requirements. However a pharmacist must ensure that a purchaser receives the accompanying product information insert and be available to answer questions or provide counseling as appropriate.

**Can Plan B<sup>®</sup> be sold to males?**

Yes. There is no gender distinction on OTC sales. The only restriction on the sale of the product is that the purchaser must be at least 18 years of age.

**Is there a quantity limit on the sale of Plan B<sup>®</sup> OTC?**

No. There is no limitation on quantity of purchase established by the FDA or the manufacturer. Limits may be established by individual pharmacies.

**Is a sales log or other form of record keeping required?**

No. The pharmacy must ensure that the product is being provided after appropriately confirming the age of the purchaser. There is no recordkeeping or documentation requirement for the sale of OTC Plan B<sup>®</sup>.

**How will the sales of Plan B<sup>®</sup> be monitored and what penalties are in place for offenders?**

Duramed, the manufacturer of Plan B<sup>®</sup>, was required by the FDA to develop a point of sale monitoring program to ensure that the sales of Plan B<sup>®</sup> are conducted according to the age requirements set forth by the FDA. To ensure that the age restrictions are followed, Duramed is implementing the CARE program (Convenient Access Responsible Education) which outlines distribution, education and monitoring of sales of OTC Plan B<sup>®</sup>.

Any penalties for repeated failure of a pharmacy to comply with the age restriction, as reported by the CARE program to the State Board of Pharmacy, will be determined by the State Board.

Details of the CARE program can be found on the FDA website at:

<http://www.fda.gov/cder/drug/infopage/planB/memo.pdf> .

**Can my existing inventory be used?**

Existing inventories are labeled for prescription only. These may continue being dispensed only pursuant to a prescription as long as they are in date. The product labeled for prescription only may not be sold OTC.

See full prescribing information at [www.go2planB.com](http://www.go2planB.com) or call **1-800-330-1271**