Plan B® Dual Label Rx/OTC Product FAQ’s

What does this approval mean- what has changed?
- The product will remain available by Rx for women 17 and younger, BUT will be available for consumers 18 and older without a prescription (OTC). There will be a single pack for both Rx and OTC use.
- The NDC number for the new Dual Label package will remain the same as the current Rx package that is sold today.

Are there changes to the doses or components of the product?
- No. The tablets in the new Dual Label package are exactly the same as the tablets in the Rx package that is sold today. PLAN B® contains 2 tablets of 0.75mg levonorgestrel each. One tablet should be taken as soon as possible within 72 hours and the second tablet should be taken 12 hours later.

As of TODAY, can the current product be dispensed to patients without a prescription based on this approval?
- No. The current product on the market today can only be dispensed with a valid Rx. When the new Dual Labeled (RX/OTC label) product is introduced later this year, then the new product can be sold to consumers 18 and older without a prescription, and women 17 and younger with a prescription.

How is the new Dual Labeled package different?
- The new Dual Labeled product has the DRUG FACTS listed on the outside of the package (for OTC- 18 and older purchase/use) and also contains an area on the outside of the package where the Rx label can be affixed (for Rx- women 17 and younger). In addition to the two tablets, the new Dual Label package will also contain Prescribing Information, and a Patient Information Booklet which explains what PLAN B® is and how and when to take it. It also contains important information informing patients that they should use other methods for routine birth control and that Plan B® does not protect against HIV/STI’s.
Where will Plan B® reside in the Pharmacy?
- Plan B® must be stored behind the Counter, as it remains an Rx product for women 17 and younger.

How should age be verified at point of purchase for OTC use?
- Pharmacists and their staff will need to be prepared to answer questions at point of purchase and to follow a protocol, where appropriate, for asking consumers to provide government issued ID to verify they are 18 years of age or older.

When will the new package be available?
- The new Dual Label Plan B® package will be made available before year end. Duramed Pharmaceuticals is targeting introduction for sometime in October 2006. In the interim, accounts should continue to order and dispense the current Rx PLAN B® product as an Rx only product.

What is the CARE™ Program?
- The CARE™ program stands for Convenient Access Responsible Education, and is a program that provides requirements for appropriate distribution, comprehensive education to healthcare professionals and patients, and monitoring for compliance with prescription age requirements. The CARE™ Program is a key element of the FDA approval for the new Dual Label PLAN B® product and Duramed will be contacting the key stakeholders (wholesalers/distributors, pharmacies and healthcare providers) shortly to provide additional information and education on this program.

Where will PLAN B® be sold?
- Duramed Pharmaceuticals will only sell PLAN B® to licensed drug wholesalers/distributors, pharmacies and clinics with professional licensed healthcare providers.