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## NEWS RELEASE

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### **Barr Announces Voluntary Recall of 3 Lots of Nortrel™ 7/7/7 – 28 Day**

**Woodcliff Lake, NJ, July 9, 2003** -- Barr Laboratories, Inc. (NYSE-BRL) today announced that it is initiating a voluntary recall of 3 lots of its Nortrel™ 7/7/7 – 28 day (norethindrone and ethinyl estradiol tablets, USP) oral contraceptive product to the pharmacy level and is encouraging women who are currently taking the product to carefully examine their blister cards to confirm that the color-coded tablets are packaged in the proper color sequence. The first three rows (labeled “Start”, “Week 2” and “Week 3”) of a properly packaged product contain colored tablets. The last row (labeled “Week 4”) of a properly packaged product contains white tablets. The recall is being implemented because two individuals have notified the Company that the color-coded tablets in their blister cards of the product were in an improper sequence which may increase the risk for pregnancy.

The recall is effective immediately and involves Lot Numbers 290122001, 290122002 and 290122003. The Lot Numbers should appear in a window labeled "LOT: " on the upper right-hand corner of the back side of the package. Any Nortrel 7/7/7 – 28 day product that does not bear a Lot Number in that location is also subject to the recall. No other lots of Nortrel or other Barr oral contraceptive products are affected by this recall. Doctors, pharmacists or women seeking additional information on this recall are encouraged to call Barr Laboratories, Inc.'s Drug Information at 1-800-222-0190 extension 33302.

Nortrel 7/7/7 – 28 day is packaged in a blister card containing four horizontal rows of seven tablets each, with each row representing one week of tablets. The first (i.e. top) row should contain yellow tablets. The second row should contain blue tablets. The third row should contain peach tablets. The fourth (i.e. bottom) row should contain white tablets. The colored tablets contain the active hormonal ingredients. The white tablets are placebos that contain no active ingredient.

Any woman who has received a Nortrel 7/7/7 – 28 day blister card with tablets in the wrong sequence could be at an increased risk of pregnancy. In addition, changes to the menstrual cycle, including delayed bleeding, irregular bleeding or spotting, may occur.



The Company recommends that women taking Nortrel 7/7/7 – 28 day carefully check their blister cards and take the following steps:

- If their blister card contains out-of-sequence tablets, they should continue taking the product, immediately consult with their health care practitioner for further instructions and return the product to their pharmacist for a replacement blister card. The company will replace any out-of-sequence blister card at no additional cost and will also cover the cost of a pregnancy test for any woman who purchased and used a blister card with out-of-sequence tablets.
- If their blister card contains the correct sequence of tablets, they should continue taking the product.
- Women who are not certain whether their blister card contains the correct sequence of tablets should contact the Company or their pharmacist immediately, but should continue taking the product until otherwise instructed by their health care practitioner or pharmacist.
- Women who believe they may have previously taken Nortrel 7/7/7 – 28 day from an out-of-sequence blister card and who are concerned about pregnancy or irregular bleeding should consult their health care practitioner for further instructions.

Out of approximately 470,000 packages of marketed Nortrel 7/7/7 – 28 day that are subject to the recall, Barr has received two reports in which the tablets in the blister are reversed, causing the white placebo row to be in the first row labeled “start” (i.e., week one) rather than in the last row labeled “Week 4” . Additionally, the lot number and expiration date were not visible on the back of these two cards.

The U.S. Food and Drug Administration (FDA) has been notified of the recall. All manufacturing and packaging processes related to the product have been reviewed, and the Company said it believes that the mispackaging was an isolated incident limited to the lots in question and corrective actions have been taken.

Nortrel 7/7/7 – 28 day is a generic version of Ortho-McNeil Pharmaceutical's Ortho-Novum<sup>®</sup> 7/7/7 oral contraceptive and is indicated for the prevention of pregnancy in women who elect to use this product as a method of contraception. It is supplied in a 28-day regimen.

Barr said that it is committed to the manufacture of quality pharmaceuticals and regrets the inconvenience the recall may have for customers. The Company said it was working closely with its customers to replace any product in their inventory from the lots in question. The Company recommends that women who have been using the affected lots of Nortrel 7/7/7 - 28 day and have questions seek the advice of their healthcare professional.

Barr Laboratories, Inc. is engaged in the development, manufacture and marketing of generic and proprietary pharmaceuticals.



*Safe Harbor Statement: To the extent that any statements made in this report contain information that is not historical, these statements are essentially forward-looking. These statements are subject to risks and uncertainties that cannot be predicted or quantified and, consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include: the difficulty in predicting the timing and outcome of legal proceedings, including those relating to patent challenge settlements and patent infringement cases; the difficulty of predicting the timing of U.S. Food and Drug Administration, or FDA, approvals; court and FDA decisions on exclusivity periods; the ability of competitors to extend exclusivity periods past initial patent terms; market and customer acceptance and demand for our pharmaceutical products; reimbursement policies of third party payors; our ability to market our proprietary products; the successful integration of acquired businesses and products into our operations; the use of estimates in the preparation of our financial statements; the impact of competitive products and pricing; the ability to develop and launch new products on a timely basis; the availability of raw materials; availability of any product we purchase and sell as a distributor; the regulatory environment; fluctuations in operating results, including spending for research and development, sales and marketing and patent challenge activities; and, other risks detailed from time-to-time in our filings with the Securities and Exchange Commission, or SEC. Forward-looking statements can be identified by the use of words such as “expects,” “plans,” “will,” “may,” “anticipates,” “believes,” “should,” “intends,” “estimates,” and other words of similar meaning. These statements are subject to risks and uncertainties that cannot be predicted or quantified and, consequently, actual results may differ materially from those expressed or implied by such forward-looking statement. The Company undertakes no obligation to publicly update any forward-looking statements.*

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