DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

21-045/S-011

Duramed Research, Inc.
Attention: Joseph A. Carrado, M.Sc., R.Ph.
Vice President, Clinical Regulatory Affairs
One Belmont Ave, 11th floor
Bala Cynwyd, PA 19004

Dear Mr. Carrado:

Please refer to your supplemental new drug application dated April 16, 2003, received April 22, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plan B® (levonorgestrel) Tablets, 0.75 mg.

We also acknowledge receipt of your submissions dated July 25 (3), and 31, August 8 (2), September 4, 8, 9, and 15, October 6, 10, 15 (2), 17, 21, 24, 29, 30, and 31, December 3, and 9, 2003; January 9, and 30, February 6, 10, 13, 20, and 24, March 11 and 26, May 6 and 11, June 30, July 21, 2004; January 6, 12, 13, 14, 18, 19 and 21, and August 26, 2005; and August 2, 17, 18, and 23, 2006.

Your submission of July 21, 2004, constituted a complete response to our May 6, 2004, Not Approvable letter. The resubmitted supplemental new drug application provides for a switch to Over-the-Counter (OTC) status for women ages 16 years or greater and maintenance of prescription status for women under age 16. On August 26, 2005, then Commissioner Lester M. Crawford, DVM, PhD, sent you a letter indicating that the Agency was unable, at that time, to reach a decision on the approvability of the application because of unresolved issues that related to your NDA. The letter mentioned three issues: whether the same active ingredient could be marketed both Rx and OTC based solely on the age of the individual using the drug; how, as a practical matter, an age-based distinction could be enforced; and whether the Rx and OTC versions of the same active ingredient may be marketed in a single package. The letter also stated that the agency had decided to ask for public comments on whether we should initiate a rulemaking to codify our interpretation of section 503(b) of the Federal Food, Drug, and Cosmetic Act regarding when an active ingredient can be simultaneously marketed in both a prescription drug product and an OTC drug product through an advance notice of proposed rulemaking (ANPRM) that published on September 1, 2005 (70 FR 52050). The comment period closed on November 1, 2005, and the agency received about 47,000 comments. The agency hired a contractor to summarize and categorize the comments and the contractor submitted a final report on May 19, 2006.

On July 31, 2006, Dr. Andrew von Eschenbach, Acting Commissioner of Food and Drugs, sent you a letter indicating that the agency had reviewed the comments received in response to the ANPRM and determined it was not necessary to engage in rulemaking to resolve the novel regulatory issues raised by your application and that we were now proceeding with further evaluation of your application.

We met with you on August 8, 2006, and discussed how to address the issues raised in Dr. von Eschenbach's letter regarding the restriction on OTC sales of Plan B® to ages 18 and over, the packaging, and the Convenient Access Responsible Education (CARE℠) Program.

On August 17, 18, and 23, 2006, you amended your application to propose revisions to the labeling and to the CARE℠ Program.

We have completed our review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that Plan B® is safe and effective for use under the conditions set forth in the draft labeling submitted on August 23, 2006. This application is approved, effective on the date of this letter, to allow OTC availability of Plan B® for consumers 18 years and older. Plan B® remains available by prescription only for women 17 years and younger.

The final printed labeling (FPL) must be identical to the enclosed labeling (prescription package insert, outer carton label, inner card label, and consumer information leaflet). The inner card and outer carton labels must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved NDA 21-045 /S-011**." Approval of this submission by FDA is not required before the labeling is used.

We also remind you of the activities you agreed to as specified in the CARE℠ Program described in your submission dated August 23, 2006. You agreed to:

- Monitor trends in the use of emergency contraception to evaluate the effectiveness of the CARE℠ program. Specifically, you have agreed to conduct a market research survey or surveys of a subset of healthcare professionals annually, and when practicable, in collaboration with established professional groups. Your surveys will be designed to determine whether the Rx requirement for those ages 17 and younger is being adhered to at the point of purchase and to provide signals of program effectiveness and potential problems associated with consumers' understanding of the purpose and proper use of Plan B®.

- Using relevant survey data regularly collected by others (e.g., Centers for Disease Control's Behavioral Risk Factor Safety Surveillance (CDC BRFSS), Youth Risk Behavior Safety Surveillance (YRBSS)), to monitor for potential indicators that Plan B® is being used in an inappropriate manner. Potential areas of monitoring and reporting include evaluating possible correlations between increases in sexually transmitted infections (STIs) based on geographic areas and data and trends in pregnancy and/or abortion rates based on geographic areas.

- Conduct a "Point-of-Purchase Monitoring Program" to track how Plan B® is being sold at the time of purchase, including using anonymous shoppers who will be directed to visit locations where Plan B® is available and purchase the product. Using the data collected, you will document and analyze the level of comprehension of the Plan B® prescription age requirement and how it is handled at the point of purchase. The program will be conducted twice in the first

year and annually thereafter. The sponsor will report repeat violators to the relevant State Boards of Pharmacy.

- Report to FDA on the results of these activities on a six-month interval beginning 30 calendar days after the six-month interval commencing on the date of this approval.

Finally, we note and agree with the other elements of the CARE^{SM} Program, described in your submission of August 23, 2006, which are designed to ensure compliance with the approved labeling, and particularly the restriction of OTC use to ages 18 and older. The program includes the following elements:

- The sponsor and third party distributors, wholesalers, and chain drug companies will only distribute Plan B® to licensed pharmacies or other licensed healthcare clinics. As a result, Plan B® will not be sold at gas stations or convenience stores. Given that Plan B® will have both Rx and OTC labeling, the pharmacies will keep Plan B® behind-the-counter.

- The sponsor will conduct an education campaign that will focus initially on healthcare professionals (including prescribers and pharmacists) to raise awareness and knowledge levels about emergency contraception. The education campaign will clearly communicate the prescription age requirement and the appropriate use of emergency contraception. The campaign will include continuing education by certified professionals and educational materials (including websites and toll free numbers) that can be accessed easily and at any time.

- The sponsor will make available to State Boards of Pharmacy continuing education programs for use at annual meetings and other regional programs.

- The sponsor will provide to prescribers and healthcare professional associations materials for distribution to patients that will encourage patients to discuss any questions about emergency contraception with a healthcare professional.

- The sponsor plans to educate consumers in part by targeting consumers ages 18 to 44 to convey critical awareness and educational messages as well as information about product availability, time sensitivity of use, and the age requirements to obtain Plan B® as a prescription or OTC product.

Any change to the CARE^{SM} Program must be discussed with FDA prior to its implementation and is subject to FDA's review.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. The safety and effectiveness of Plan B® provided pursuant to a prescription in pediatric patients (those under age 18) need not be addressed under the Pediatric Research Equity Act of 2003 (PREA) because this supplemental application does not propose a new indication for women in this age group (i.e., Plan B® is to remain prescription for women under 18).

In addition, we request that you submit to FDA four copies of the introductory promotional materials that you propose to use for Plan B®. Submit all proposed materials in draft or mock-up form, not final

print. Send one copy to the Division of Reproductive and Urologic Products, one to the Division of Nonprescription Clinical Evaluation, and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please submit one market package of Plan B® when it is available.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call the Office of Nonprescription Products, Division of Nonprescription Clinical Evaluation at (301) 796-2080.

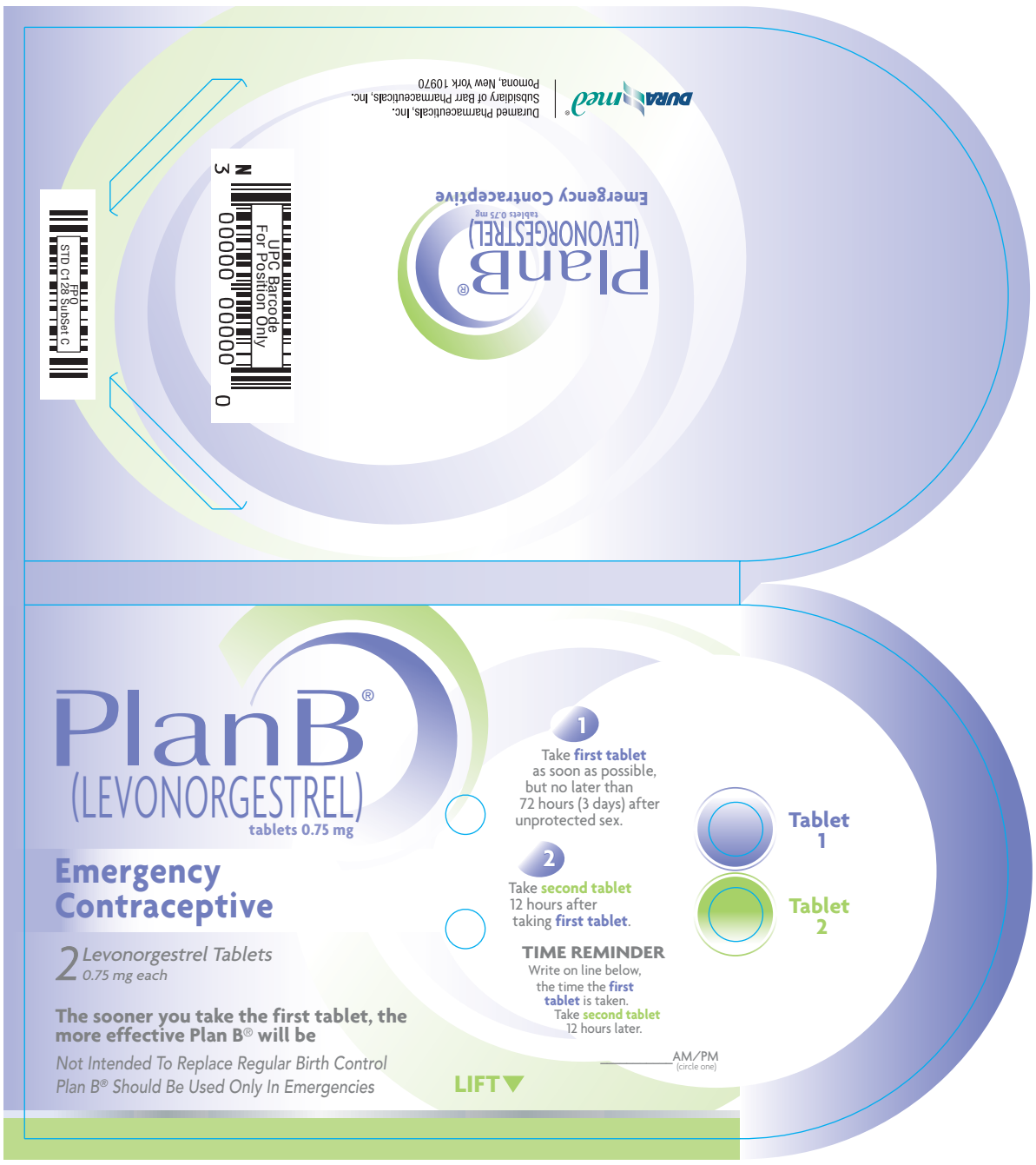
Sincerely,

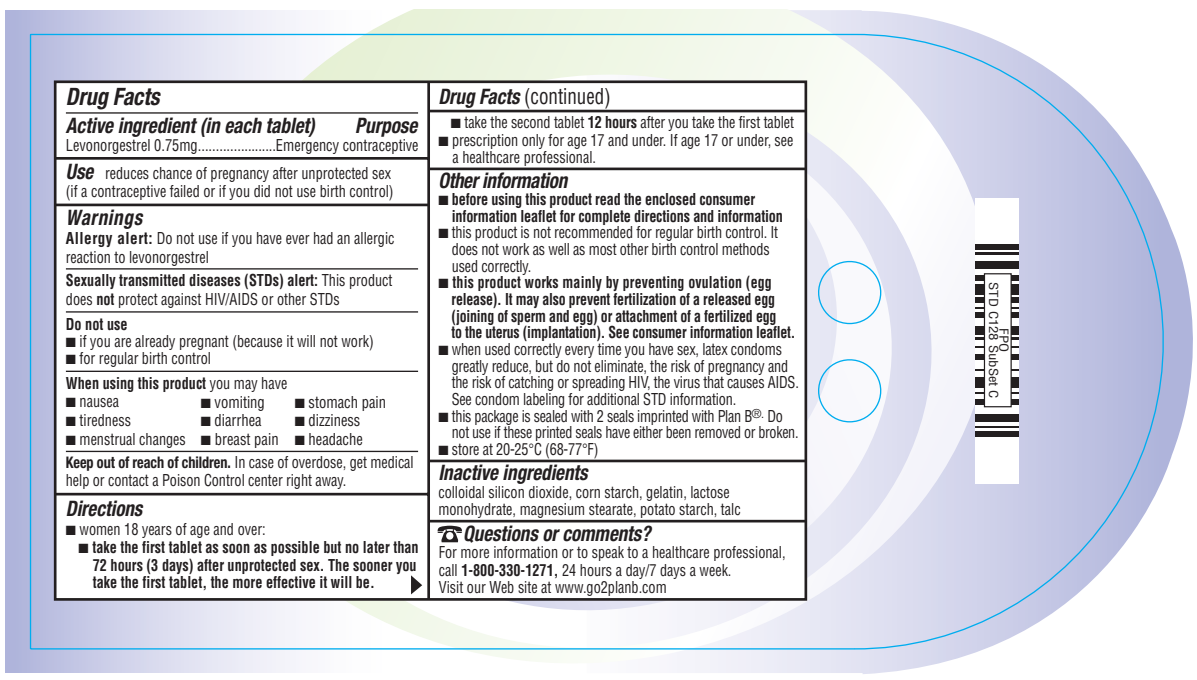
{See appended electronic signature page}

Steven Galson, M.D., M.P.H.
Director
Center for Drug Evaluation and Research

Enclosure

DRUG FACTS TEXT DEFINED	TYPE SIZE	TYPE FONT
• DRUG FACTS Title	9 pt	Helvetica Bold Condensed Oblique
• DRUG FACTS CONTINUED	8 pt	Helvetica Bold Cond. Oblique/Helvetica Condensed
• HEADINGS	8 pt	Helvetica Bold Condensed Oblique
• SUBHEADS/BODY TEXT	6 pt	Helvetica Bold Condensed/Helvetica Condensed
• LEADING	7 pt	
• # OF CHARACTERS PER INCH	<39	
• BULLETS	5 pt	Zapf Dingbats
• SPACE AFTER BULLETED SECTION	2 ems	
• BARLINES, HAIRLINES	1 pt, .5 pt	
• SPACE BETWEEN HAIRLINES AND BOX END	2 spaces	





Drug Facts

Active ingredient (in each tablet) **Purpose**
Levonorgestrel 0.75mg.....Emergency contraceptive

Use reduces chance of pregnancy after unprotected sex (if a contraceptive failed or if you did not use birth control)

Warnings

Allergy alert: Do not use if you have ever had an allergic reaction to levonorgestrel

Sexually transmitted diseases (STDs) alert: This product does **not** protect against HIV/AIDS or other STDs

Do not use
- if you are already pregnant (because it will not work)
- for regular birth control

When using this product you may have
- nausea
- vomiting
- stomach pain
- tiredness
- diarrhea
- dizziness
- menstrual changes
- breast pain
- headache

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control center right away.

Directions
- women 18 years of age and over:
  - **take the first tablet as soon as possible but no later than 72 hours (3 days) after unprotected sex. The sooner you take the first tablet, the more effective it will be.**

Drug Facts (continued)
- take the second tablet **12 hours** after you take the first tablet
- prescription only for age 17 and under. If age 17 or under, see a healthcare professional.

Other information
- **before using this product read the enclosed consumer information leaflet for complete directions and information**
- this product is not recommended for regular birth control. It does not work as well as most other birth control methods used correctly.
- **this product works mainly by preventing ovulation (egg release). It may also prevent fertilization of a released egg (joining of sperm and egg) or attachment of a fertilized egg to the uterus (implantation). See consumer information leaflet.**
- when used correctly every time you have sex, latex condoms greatly reduce, but do not eliminate, the risk of pregnancy and the risk of catching or spreading HIV, the virus that causes AIDS. See condom labeling for additional STD information.
- this package is sealed with 2 seals imprinted with Plan B®. Do not use if these printed seals have either been removed or broken.
- store at 20-25°C (68-77°F)

Inactive ingredients
colloidal silicon dioxide, corn starch, gelatin, lactose monohydrate, magnesium stearate, potato starch, talc

Questions or comments?
For more information or to speak to a healthcare professional, call **1-800-330-1271,** 24 hours a day/7 days a week.
Visit our Web site at www.go2planb.com

FPO
STD C128 SubSet C

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	2 spaces	

• SPACE BETWEEN HAIRLINES AND BOX END

Protect Yourself & Your Future

Important Information for Women About Plan B®, Birth Control & Sexually Transmitted Diseases

Please see enclosed important Product Information for Plan B®.

Plan B®
(LEVONORGESTREL)
tablets 0.75 mg
Emergency Contraceptive

From the makers of Plan B®, Duramed Pharmaceuticals, Inc., a subsidiary of Barr Pharmaceuticals, Inc.

What is Plan B®?

Plan B® is emergency contraception. Emergency contraception is a **backup** method of preventing pregnancy and is not for routine use. Drugs used for emergency contraception are called emergency contraceptive pills, postcoital pills, or morning after pills.

Plan B® can reduce your chance of pregnancy after unprotected sex (if your regular birth control method fails or if you have had sex without birth control). For example, if you were using a condom and it broke, or if you forgot to take 2 or more of your birth control pills this month, or if you did not use any birth control method, Plan B® may work for you.

How does Plan B® work?

Plan B® contains a dose of the hormone levonorgestrel that is higher than in a single birth control pill. Levonorgestrel has been used in birth control pills for over 35 years. Plan B® works like a birth control pill to prevent pregnancy mainly by stopping the release of an egg from the ovary. It is possible that Plan B® may also work by preventing fertilization of an egg (the uniting of sperm with the egg) or by preventing attachment (implantation) to the uterus (womb), which usually occurs beginning 7 days after release of an egg from the ovary. Plan B® will not do anything to a fertilized egg already attached to the uterus. The pregnancy will continue.

PlanB®
(LEVONORGESTREL)
tablets 0.75 mg

When is it appropriate to use Plan B®?

You can use Plan B® **after** you have had unprotected sex 1 or more times in the last 3 days (72 hours), and you don't want to become pregnant.

Plan B® can be used as a backup method to birth control if, for example,

- Your regular birth control failed (your partner's condom broke or slipped)
- You made a mistake with your regular method (you missed 2 or more birth control pills this month)
- You did not use any birth control method

When is it not appropriate to use Plan B®?

- Plan B® should not be used as a regular birth control method. It does not work as well as most other forms of birth control when they are used consistently and correctly. Plan B® is a backup or emergency method of contraception
- Plan B® should not be used if you are already pregnant because it will not work
- Plan B® should not be used if you are allergic to levonorgestrel
- Plan B® does not protect against HIV (the virus that causes AIDS) or other sexually transmitted diseases (STDs). The best ways to protect yourself against getting HIV or other STDs are to use a latex condom correctly with every sexual act or not to have sex at all

PlanB®
(LEVONORGESTREL)
tablets 0.75 mg

How can I get the best results from Plan B®?

You have only a few days to prevent pregnancy after unprotected sex. **Plan B® works better the sooner you take it.** Take the first Plan B® tablet **as soon as possible but not later than 3 days (72 hours)** after unprotected sex. Take the second tablet **12 hours** later.

How effective is Plan B®?

Plan B® works best the sooner you use it. If it is taken within 72 hours (3 days) after sex, it will significantly decrease the chance that you will get pregnant. Seven out of every 8 women who would have gotten pregnant will not become pregnant. Plan B® works even better than this if taken within the first 24 hours after sex.

How will I know if Plan B® worked?

Most women will have their next menstrual period at the expected time or within a week of the expected time. If your menstrual period is delayed beyond 1 week, you may be pregnant and you should get a pregnancy test and follow up with your healthcare professional.

What if I am already pregnant and use Plan B®?

There is no medical evidence that Plan B® would harm a developing baby. If you take Plan B® accidentally after you are already pregnant, or it does not work and you become pregnant, it is not likely to cause any harm to you or your pregnancy. Plan B® should not have any effect on a pregnancy after implantation.

PlanB®
(LEVONORGESTREL)
tablets 0.75 mg

What should I do if my menstrual period is delayed beyond 1 week and I have severe lower stomach pain?

If you have severe lower stomach pain about 3 to 5 weeks after taking Plan B®, you may have a pregnancy outside the uterus (a tubal pregnancy). See a healthcare professional right away because a tubal pregnancy requires immediate medical treatment.

Can I use Plan B® for regular birth control?

Plan B® should not be used for regular birth control. Plan B® is not as effective as using a regular birth control method correctly and consistently. It is a backup method to be used if your regular birth control fails or if you have sex without birth control. You should not

have unprotected sex following treatment because Plan B® will not protect you from getting pregnant.

How often can I use Plan B®?

Plan B® is meant for infrequent emergency protection. If you need to use emergency contraception often, you should consult with your healthcare professional for your best methods of birth control and STD prevention.

Will I experience any side effects from Plan B®?

When used as directed, Plan B® is safe for women. Plan B® has no serious or lasting medical side effects. Some women will experience non-serious side effects, such as nausea, stomach pain, headache, dizziness, or breast

tenderness. These are similar to the side effects of regular birth control pills. Some women have menstrual changes such as spotting or bleeding before their next period. Some women may have a heavier or lighter next period, or a period that is early or late. **If your period is more than a week late, you should get a pregnancy test.**

What warnings should I know about when using Plan B®?

Plan B® does not protect against the AIDS virus (HIV) or other sexually transmitted diseases (STDs).

Do not use:

- If you are already pregnant (because it will not work)
- If you are allergic to levonorgestrel or any of the ingredients in Plan B®
- For regular birth control

When using this product you may have:

- Nausea
- Vomiting
- Stomach pain
- Tiredness
- Diarrhea
- Dizziness
- Breast pain
- Headache
- Menstrual changes

PlanB® (LEVONORGESTREL) tablets 0.75 mg

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

What are the directions for using Plan B®?

- **Women 18 years of age and over:**
  - **take the first tablet as soon as possible but not later than 72 hours (3 days) after unprotected sex**
  - take the second tablet **12 hours** after you take the first tablet
  - if you vomit within 1 hour of taking either dose of medication, call a healthcare professional to discuss whether to repeat the dose
- Prescription only for age 17 and under. If age 17 or under, see a healthcare professional.

What should I do if I have questions about Plan B®?

If you have questions or need more information about this product, call our toll-free number, 1-800-330-1271, visit our Web site at www.go2planB.com, or ask a healthcare professional.

Other information

- This package is sealed with 2 imprinted seals. **Do not use if these imprinted seals have been removed, torn, or broken.**
- Store at 20-25°C (68-77°F)

PlanB®
(LEVONORGESTREL)
tablets 0.75 mg

Active ingredient: levonorgestrel 0.75 mg in each tablet

Inactive ingredients: colloidal silicon dioxide, potato starch, gelatin, magnesium stearate, talc, corn starch, lactose monohydrate

Protect yourself in more ways than one!

If you are sexually active, but you're not ready for a pregnancy, it is important to use routine pregnancy protection. There are many types of birth control. Whichever type you choose, it's important to use your routine birth control method as directed. This ensures that you have effective protection against pregnancy every time you have sex.

But, things do not always go as planned. You might have forgotten to take your pill, or another birth control method you use might have failed (for example, a condom can break during sex). That is why there is Plan B®. Plan B® is an emergency contraceptive that offers you a second chance to prevent pregnancy after unprotected sex or when you fail to use your birth control method correctly.

Remember, Plan B® is only for emergency pregnancy prevention. It works well for this purpose. There are many other products that work very well for routine birth control. The most effective of these are available by prescription from your healthcare professional. Other effective methods are available for purchase without a prescription.

PlanB®
(LEVONORGESTREL)
tablets 0.75 mg

There is also another form of protection to think about when you have sex: protection against sexually transmitted diseases (STDs). Some common STDs are HIV/AIDS, chlamydia, genital herpes, gonorrhea, hepatitis, human papilloma virus (HPV), genital warts, syphilis, and trichomonas. Some of these STDs can be very serious and can lead to infertility (permanent inability to have a baby), problems during pregnancy, chronic illness, and even death.

All sexually active women are at risk of catching STDs because they may not be able to know that their partner has an STD (the partner himself may not know). If your partner uses a latex condom **correctly each and every time you have sex with him, this will help reduce, but not eliminate, the chance that you will catch an STD**.

No other birth control methods will protect you from STDs. The female condom may give you some STD protection, but it is not as effective as a male latex condom.

For more information on STDs, call the Centers for Disease Control and Prevention (CDC) AIDS/STD Hotline. The CDC phone numbers are 1-800-342-AIDS (2437) for English, 1-800-344-7432 for Spanish, or 1-800-243-7889 for hearing impaired, TDD.

PlanB®
(LEVONORGESTREL)
tablets 0.75 mg

Be sure to protect yourself against pregnancy and STDs by using some form of birth control plus a latex condom. Of course, not having sex is the most effective way to prevent pregnancy and stay free of STDs. We hope this information will help you make the right choices to stay healthy for your future.

Plan B® is used to prevent pregnancy after unprotected sex or contraceptive failure.

Plan B® should not be used if you are already pregnant (because it will not work), if you are allergic to levonorgestrel or any of the ingredients in Plan B®, or for regular birth control.

Menstrual bleeding may be heavier or lighter after taking Plan B®. If your period is more than a week late, pregnancy should be considered.

Plan B® does not protect against the AIDS virus (HIV) or other sexually transmitted diseases (STDs).

Common side effects associated with the use of Plan B® included nausea, vomiting, stomach pain, tiredness, diarrhea, dizziness, breast pain, headache, and menstrual changes.

PlanB®
(LEVONORGESTREL)
tablets 0.75 mg

1-800-330-1271 **www.go2planB.com**

Plan B® is a registered trademark of Women's Capital Corporation, a subsidiary of Duramed Pharmaceuticals, Inc.

Duramed Pharmaceuticals, Inc.
Subsidiary of Barr Pharmaceuticals, Inc.
Pomona, New York 10970

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PLB-A60710 September 2006 Printed in USA

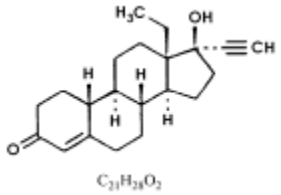
Plan B® (Levonorgestrel) Tablets, 0.75 mg

Rx only for women age 17 and younger

For women age 17 and younger, Plan B ® is a prescription–only emergency contraceptive. Plan B® is intended to prevent pregnancy after known or suspected contraceptive failure or unprotected intercourse. Emergency contraceptive pills (like all oral contraceptives) do not protect against infection with HIV (the virus that causes AIDS) and other sexually transmitted diseases.

DESCRIPTION

Emergency contraceptive tablet. Each Plan B® tablet contains 0.75 mg of a single active steroid ingredient, levonorgestrel [18,19-Dinorpregn-4-en-20-yn-3-one-13-ethyl-17-hydroxy-, (17α)-(-)-], a totally synthetic progestogen. The inactive ingredients present are colloidal silicon dioxide, potato starch, gelatin, magnesium stearate, talc, corn starch, and lactose monohydrate. Levonorgestrel has a molecular weight of 312.45, and the following structural and molecular formulas:



CLINICAL PHARMACOLOGY

Emergency contraceptives are not effective if the woman is already pregnant. Plan B® is believed to act as an emergency contraceptive principally by preventing ovulation or fertilization (by altering tubal transport of sperm and/or ova). In addition, it may inhibit implantation (by altering the endometrium). It is not effective once the process of implantation has begun.

Pharmacokinetics

Absorption:

No specific investigation of the absolute bioavailability of Plan B® in humans has been conducted. However, literature indicates that levonorgestrel is rapidly and completely absorbed after oral administration (bioavailability about 100%) and is not subject to first pass metabolism.

After a single dose of Plan B® (0.75 mg) administered to 16 women under fasting conditions, maximum serum concentrations of levonorgestrel are 14.1 $\pm$ 7.7 ng/mL (mean $\pm$ SD) at an average of 1.6 $\pm$ 0.7 hours. No formal study of the effect of food on the absorption of levonorgestrel has been undertaken.

Table 1 Pharmacokinetic Parameter Values Following Single Dose Administration of Plan B® (Levonorgestrel) Tablets 0.75 mg to Healthy Female Volunteers

N	Mean (± S.D.)					
	C_{max} (ng/mL)	T_{max} (h)	CL (L/h)	V_d (L)	$T_{½}$ (h)	$AUC_{0-\infty}$ (ng/mL/h)
16	14.1 ± 7.7	1.6 ± 0.7	7.7 ± 2.7	260.0	24.4 ± 5.3	123.1 ± 50.1

Distribution:
Levonorgestrel in serum is primarily protein bound. Approximately 50% is bound to albumin and 47.5% is bound to sex hormone binding globulin (SHBG).

Metabolism:
Following a single oral dosage, levonorgestrel does not appear to be extensively metabolized by the liver. The primary metabolites are 3α,5β- and 3α,5α-tetrahydrolevonorgestrel with 16β-hydroxynorgestrel also identified. Together, these account for less than 10% of parent plasma levels. Urinary metabolites hydroxylated at the 2α and 16β positions have also been identified. Small amounts of the metabolites are present in plasma as sulfate and glucuronide conjugates.

Excretion:
The elimination half-life of levonorgestrel following single dose administration as Plan B® (0.75 mg) is 24.4 ± 5.3 hours. Excretion following single dose administration as emergency contraception is unknown, but based on chronic, low-dose contraceptive use, levonorgestrel and its metabolites are primarily excreted in the urine, with smaller amounts recovered in the feces.

SPECIAL POPULATIONS

Geriatric
This product is not intended for use in geriatric (age 65 years or older) populations and pharmacokinetic data are not available for this population.

Pediatric
This product is not intended for use in pediatric (premenarcheal) populations, and pharmacokinetic data are not available for this population.

Race
No formal studies have evaluated the effect of race. However, clinical trials demonstrated a higher pregnancy rate in the Chinese population with both Plan B® and the Yuzpe regimen (another form of emergency contraception consisting of two doses of ethinyl estradiol 0.1 mg + levonorgestrel 0.5 mg). The reason for this apparent increase in the pregnancy rate of emergency contraceptives in Chinese women is unknown.

Hepatic Insufficiency and Renal Insufficiency
No formal studies have evaluated the effect of hepatic insufficiency or renal insufficiency on the disposition of emergency contraceptive tablets.

Drug-Drug Interactions
No formal studies of drug-drug interactions were conducted.

INDICATIONS & USAGE
For women age 17 and younger, Plan B® is a prescription-only emergency contraceptive that can be used to prevent pregnancy following unprotected intercourse or a known or suspected contraceptive failure. To obtain optimal efficacy, the first tablet should be taken as soon as possible within 72 hours of intercourse. The second tablet must be taken 12 hours later.

Clinical Studies
A double-blind, controlled clinical trial in 1,955 evaluable women compared the efficacy and safety of Plan B® (one 0.75 mg tablet of levonorgestrel taken within 72 hours of intercourse, and one tablet taken 12 hours later) to the Yuzpe regimen (two tablets of 0.25 mg levonorgestrel and 0.05 mg ethinyl estradiol, taken within 72 hours of intercourse, and two tablets taken 12 hours later). Plan B® was at least as effective as the Yuzpe regimen in preventing pregnancy. After a single act of intercourse, the expected pregnancy rate of 8% (with no contraception) was reduced to approximately 1% with Plan B®.

Emergency contraceptives are not as effective as routine contraception since their failure rate, while low based on a single use, would accumulate over time with repeated use (see Warnings). See Table 2 below.

Table 2: Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception and the percentage continuing use at the end of the first year, United States.

	% of Women Experiencing an Unintended Pregnancy within the First Year of Use		% of Women Continuing Use at One Year [3]
Method (1)	Typical Use [1] (2)	Perfect Use [2] (3)	(4)
Chance [4]	85	85	
Spermicides [5]	26	6	40
Periodic abstinence	25		63
Calendar		9	
Ovulation method		3	
Sympto-thermal [6]		2	
Post-ovulation		1	
Withdrawal	19	4	
Cap [7]			
Parous women	40	26	42
Nulliparous women	20	9	56
Sponge			
Parous women	40	20	42
Nulliparous women	20	9	56
Diaphragm [7]	20	6	56
Condom [8]			
Female (Reality)	21	5	56
Male	14	3	61
Pill	5		71
Progestin only		0.5	
Combined		0.1	
IUD:			
Progesterone T	2.0	1.5	81
Copper T 380A	0.8	0.6	78
LNg 20	0.1	0.1	81
Depo Provera	0.3	0.3	70
Norplant and Norplant-2	0.05	0.05	88
Female sterilization	0.5	0.5	100
Male sterilization	0.15	0.10	100
Emergency Contraceptive Pills: Treatment initiated within 72 hours after unprotected intercourse reduces the risk of pregnancy by at least 75%. [9]			
Lactational Amenorrhea Method: LAM is a highly effective, *temporary* method of contraception. [10]			

Source: Trussell J, Contraceptive efficacy. In Hatcher RA, Trussell J, Stewart F, Cates W, Stewart GK, Kowal D, Guest F, Contraceptive Technology: Seventeenth Revised Edition. New York NY: Irvington Publishers, 1998.

[1] Among *typical* couples who initiate use of a method (not necessarily for the first time), the percentage who experience an unintended pregnancy during the first year if they do not stop use for any other reason.

[2] Among couples who initiate use of a method (not necessarily for the first time) and who use it *perfectly* (both consistently and correctly), the percentage who experience an unintended pregnancy during the first year if they do not stop use for any other reason.

[3] Among couples attempting to avoid pregnancy, the percentage who continue to use a method for one year.

[4] The percentages of women becoming pregnant in columns (2) and (3) are based on data from populations where contraception is not used and from women who cease using contraception in order to become pregnant. Among such populations, about 89% become pregnant within one year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within one year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

[5] Foams, creams, gels, vaginal suppositories and vaginal film.

[6] Cervical mucus (ovulation) method supplemented by calendar in the pre-ovulatory and basal body temperature in the post-ovulatory phases.

[7] With spermicidal cream or jelly.

[8] Without spermicides.

[9] The treatment schedule is one dose within 72 hours after unprotected intercourse and a second dose 12 hours after the first dose. The Food and Drug Administration has declared the following brands of oral contraceptives to be safe and effective for emergency contraception: Ovral (1 dose is 2 white pills), Alesse (1 dose is 5 pink pills), Nordette or Levlen (1 dose is 2 light-orange pills), Lo/Ovral (1 dose is 4 white pills), Triphasil or Tri-Levlen (1 dose is 4 yellow pills).

[10] However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeds is reduced, bottle feeds are introduced or the baby reaches six months of age.

CONTRAINDICATIONS

Progestin-only contraceptive pills (POPs) are used as a routine method of birth control over longer periods of time, and are contraindicated in some conditions. It is not known whether these same conditions apply to the Plan B® regimen consisting of the emergency use of two progestin pills. POPs however, are not recommended for use in the following conditions:

- Known or suspected pregnancy
- Hypersensitivity to any component of the product

WARNINGS

Plan B® is not recommended for routine use as a contraceptive.

Plan B® is not effective in terminating an existing pregnancy.

Effects on Menses

Menstrual bleeding patterns are often irregular among women using progestin-only oral contraceptives and in clinical studies of levonorgestrel for postcoital and emergency contraceptive use. Some women may experience spotting a few days after taking Plan B®. At the time of expected menses, approximately 75% of women using Plan B® had vaginal bleeding similar to their normal menses, 12-13% bled more than usual, and 12% bled less than usual. The majority of women (87%) had their next menstrual period at the expected time or within ± 7

days, while 13% had a delay of more than 7 days beyond the anticipated onset of menses. If there is a delay in the onset of menses beyond 1 week, the possibility of pregnancy should be considered.

Ectopic Pregnancy

Ectopic pregnancies account for approximately 2% of reported pregnancies (19.7 per 1,000 reported pregnancies). Up to 10% of pregnancies reported in clinical studies of routine use of progestin-only contraceptives are ectopic. A history of ectopic pregnancy need not be considered a contraindication to use of this emergency contraceptive method. Health providers, however, should be alert to the possibility of an ectopic pregnancy in women who become pregnant or complain of lower abdominal pain after taking Plan B®.

PRECAUTIONS

Pregnancy

Many studies have found no effects on fetal development associated with long-term use of contraceptive doses of oral progestins (POPs). The few studies of infant growth and development that have been conducted with POPs have not demonstrated significant adverse effects.

STD/HIV

Plan B®, like progestin-only contraceptives, does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Physical Examination and Follow-up

A physical examination is not required prior to prescribing Plan B®. A follow-up physical or pelvic examination, however, is recommended if there is any doubt concerning the general health or pregnancy status of any woman after taking Plan B®.

Carbohydrate Metabolism

The effects of Plan B® on carbohydrate metabolism are unknown. Some users of progestin-only oral contraceptives (POPs) may experience slight deterioration in glucose tolerance, with increases in plasma insulin; however, women with diabetes mellitus who use POPs do not generally experience changes in their insulin requirements. Nonetheless, diabetic women should be monitored while taking Plan B®.

Drug Interactions

Theoretically, the effectiveness of low-dose progestin-only pills is reduced by hepatic enzyme-inducing drugs such as the anticonvulsants phenytoin, carbamazepine, and barbiturates, and the antituberculosis drug rifampin. No significant interaction has been found with broad-spectrum antibiotics. It is not known whether the efficacy of Plan B® would be affected by these or any other medications.

Nursing Mothers

Small amounts of progestin pass into the breast milk in women taking progestin-only pills for long-term contraception resulting in steroid levels in infant plasma of 1-6% of the levels of maternal plasma. However, no adverse effects due to progestin-only pills have been found on breastfeeding performance, either in the quality or quantity of the milk, or on the health, growth or development of the infant.

Pediatric Use

Safety and efficacy of progestin-only pills have been established in women of reproductive age for long-term contraception. Safety and efficacy are expected to be the same for postpubertal adolescents under the age of 16 and for users 16 years and older. Use of Plan B® emergency contraception before menarche is not indicated.

Fertility Following Discontinuation

The limited available data indicate a rapid return of normal ovulation and fertility following discontinuation of progestin-only pills for emergency contraception and long-term contraception.

ADVERSE REACTIONS

The most common adverse events in the clinical trial for women receiving Plan B® included nausea (23%), abdominal pain (18%), fatigue (17%), headache (17%), and menstrual changes. The table below shows those adverse events that occurred in ≥5% of Plan B® users.

Table 3 Adverse Events in ≥5% of Women, by % Frequency

Most Common Adverse Events	Plan B® Levonorgestrel N=977 (%)
Nausea	23.1
Abdominal Pain	17.6
Fatigue	16.9
Headache	16.8
Heavier Menstrual Bleeding	13.8
Lighter Menstrual Bleeding	12.5
Dizziness	11.2
Breast Tenderness	10.7
Other complaints	9.7
Vomiting	5.6
Diarrhea	5.0

Plan B® demonstrated a superior safety profile over the Yuzpe regimen for the following adverse events:

- Nausea: Occurred in 23% of women taking Plan B® (compared to 50% with Yuzpe)
- Vomiting: Occurred in 6% of women taking Plan B® (compared to 19% with Yuzpe)

DRUG ABUSE AND DEPENDENCE

There is no information about dependence associated with the use of Plan B®.

OVERDOSAGE

There are no data on overdosage of Plan B®, although the common adverse event of nausea and its associated vomiting may be anticipated.

DOSAGE AND ADMINISTRATION

One tablet of Plan B® should be taken orally as soon as possible within 72 hours after unprotected intercourse. The second tablet should be taken 12 hours after the first dose. Efficacy is better if Plan B® is taken as directed as soon as possible after unprotected intercourse. Plan B® can be used at any time during the menstrual cycle.

The user should be instructed that if she vomits within one hour of taking either dose of medication she should contact her health care professional to discuss whether to repeat that dose.

HOW SUPPLIED

Plan B® (Levonorgestrel) Tablets, 0.75 mg are available for a single course of treatment in PVC/aluminum foil blister packages of two tablets each. The tablet is white, round and marked: INOR.

Available as:
Unit-of-use NDC 51285-038-93
Store Plan B® tablets at controlled room temperature, 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP].

Mfg. by Gedeon Richter, Ltd., Budapest, Hungary
for Duramed Pharmaceuticals, Inc.
Subsidiary of Barr Pharmaceuticals, Inc.
Pomona, New York 10970
Phone: 1-800-330-1271 Website: www.go2planb.com
Revised August 2006
BR- 038 / 21000382503

CARE℠
(CONVENIENT ACCESS, RESPONSIBLE EDUCATION) PROGRAM:

THE PROPOSED MARKETING, EDUCATION, DISTRIBUTION, MONITORING PROGRAM FOR PLAN B®

Introduction

The CARE℠ (Convenient Access, Responsible Education) Program has been carefully constructed to help ensure that Plan B® will be used responsibly and appropriately. Plan B® is being proposed as an OTC product with a prescription-only requirement for women ages 17 years and younger. The sales and marketing plan has been designed to limit the availability of Plan B®, to the extent practical, to pharmacies and clinics, and to educate healthcare professionals and consumers within the target age groups regarding the availability and responsible use of Plan B®. The need to take Plan B® in as timely a manner as possible dictates that any responsible marketing program not only address healthcare professionals but also include extensive consumer education which includes a direct access component as a means of gaining such information. Thus, the CARE℠ program contains elements that include an appropriate consumer education component. In addition, the sponsor will work closely with retail pharmacies and drug wholesalers to ensure that they will carry Plan B®, and that they will understand and follow the prescription age requirement for the dispensing of product to women age 17 years and younger.

Data suggests that there are several critical issues currently limiting access to Plan B®:

- The prescription requirement delays timely access to Plan B®;
- Pharmacies may not routinely stock Plan B®;
- Awareness of the availability of Plan B® is lacking among healthcare professionals as well as women of childbearing age, and

- Access to accurate sources of information about the product is limited.

The CARE^{SM} program is intended to address these issues by providing sources of accurate and responsible information to both healthcare providers and consumers. It is also designed to provide a framework for pharmacies to ensure availability of Plan B® as an OTC product when sought by knowledgeable consumers who are 18 years and older. Women age 17 years and younger will require a prescription from their healthcare provider in order to obtain Plan B®. The CARE^{SM} program is not intended to impact or change, who can lawfully prescribe or dispense Plan B® under prevailing state laws.

Four core elements of CARE^{SM} contribute to the achievement of program objectives.

- Labeling/Packaging/Informational toll free number (to provide essential information to consumers in an accessible, easy to understand format. The proposed Plan B® packaging is designed to meet both prescription and OTC requirements.)
- Education (to provide information intended to educate physicians, pharmacists, pharmacy staff, nurse practitioners, and patients and to provide healthcare professionals with educational materials that they can supply to their patients to stimulate discussion. Educational initiatives will also focus on clearly instructing all audiences on the age requirement that will require women age 17 years and younger to obtain a prescription for Plan B®.)
- Distribution (to ensure, that Plan B® will be available only to licensed drug wholesalers, retail operations with pharmacy services and clinics with licensed healthcare practitioners, and to successfully facilitate the Plan B® prescription-only age requirement. These settings will also provide easy access by the consumer to a pharmacist or other healthcare professional should questions arise.)
- Monitoring (to evaluate the effectiveness of the program by determining if the age restriction is understood by all audiences and is properly being adhered to. Adjustments to the program will be made as appropriate.)

I. Labeling/Packaging

The proposed Plan B® labeling was developed to provide clear and comprehensive communication of the key messages outlined above, and to make known additional sources of information. The proposed Plan B® packaging is designed to meet all requirements of both a prescription and over-the-counter product and is consistent with that studied in the Plan B® Label Comprehension Study and the Plan B® Actual Use Study. In addition, minor changes to the packaging were made to reflect the comments from the FDA Joint Advisory Committee meeting of December 16, 2003. The proposed Plan B® packaging will allow pharmacies to appropriately dispense Plan B® as either a prescription or OTC product. The proposed package also provides educational information to the consumer in a patient friendly format.

Proposed elements of the package are as follows:

- The back of the package includes the Drug Facts as well as a space for the pharmacy to place the required prescription labeling;

- The statement, "Rx only for age 17 and younger" appears on the Principal Display Panel and "prescription only for age 17 and under" has been added to the Drug Facts panel of the package;

- The inner package houses the 2 Plan B® tablets and clearly states the steps for when to take Plan B®;

- The Plan B® Package Insert and an educational booklet designed for the consumer will be housed with the inner card;

- The toll-free number for the Plan B® 24-hour Information Line and the Plan B® web address are clearly displayed in the Drug Facts panel of the package should the consumer have additional questions on Plan B®.

II. Education

Given the very low levels of awareness of the availability of emergency contraception, the CARE℠ Program provides for an intensively educational approach to the introduction of Plan B® as an OTC product for those age 18 years and older. The sponsor is proposing an educational program that will initially focus on healthcare professionals but will include limited direct-to-consumer advertising designed to stimulate discussions with healthcare providers. The program will assist healthcare providers in developing an adequate knowledge base so that they can provide responsible and accurate counseling to patients.

Efforts directed to raising consumer awareness of the product and its appropriate use will follow appropriate professional education programs. The educational materials will address not only Plan B® but will encourage healthcare professionals to urge users to adopt routine forms of contraception and avoid reliance on Plan B® as their primary form of birth control.

A. Educational Program to Healthcare Professionals.

Plan B® will be introduced and explained to healthcare professionals to raise awareness and knowledge levels as to emergency contraception. Education will also clearly communicate the prescription age requirement for Plan B®. Given the current lack of understanding of emergency contraception, this program is intended to ensure that healthcare professionals are prepared to support their patient populations.

1. Physicians, physician assistants, nurse practitioners, office staff, pharmacists and pharmacy staff are the primary audiences for this educational program. Pharmacists and pharmacy staff are especially important because they will need to be prepared to answer questions at the point of purchase and follow the protocol, when appropriate, for asking customers to provide government-issued identification of their age. Additional communication will be focused on pharmacists and their staff to ensure that they are knowledgeable of the prescription requirement for women age 17 years and younger, and that they understand how to appropriately dispense the Plan B® package in both prescription and OTC scenarios. Programs will include continuing education by certified professionals and educational materials (including websites and toll free numbers) that can be accessed easily and at any time. The sponsor will make available to the state boards of pharmacy continuing education programs for use at annual meetings and other regional programs. The sponsor will also encourage state boards of pharmacy to provide information to their members regarding the availability and appropriate use of Plan B®, as well as the prescription-only requirement for women age 17 years and younger. In addition, the sponsor will work closely with retail pharmacies to ensure that they have access to appropriate training materials for their pharmacists and pharmacy staff.

2. The sponsor's sales representatives[1] will communicate the prescription requirement for women age 17 years and younger, as well as the OTC availability of Plan B® for those 18 years of age and older. The sales representatives will also provide materials targeted for patients. Physicians, physician assistants and nurse practitioners will be asked to distribute the materials to patients. Materials will encourage patients to discuss any questions they have about emergency contraception or the specific use of Plan B® with

[1] The sponsor's sales force for female healthcare products, currently consisting of approximately 230 sales representatives, visit the offices of approximately 30,000 physicians, mostly Obstetricians and Gynecologists.

their physician or the nurse practitioner. Efforts to reach healthcare professionals to reinforce these messages will continue on an ongoing basis as part of the sponsor's professional communications program. The sponsor also will work with the relevant healthcare professional associations to provide educational programming and materials to reach those healthcare providers who will not be reached personally.

3. Key messages for consumers and healthcare providers will be tested through market research, including field-testing to ensure communication objectives are met.

B. Educational Campaign to Consumers

An information campaign to consumers will commence once the healthcare professional audience has been introduced to the product. This consumer education campaign is anticipated to begin about six months following product launch.

1. The campaign will be designed to convey critical awareness and educational messages as well as information about product availability, the time sensitivity of use, and the age requirements to obtain Plan B® as a prescription or OTC product. The intent will be to make consumers aware of the availability of emergency contraception, its appropriate use and the need to use it as soon as possible. Women age 17 years and younger will be encouraged to contact their healthcare professional to learn about emergency contraception, routine forms of birth control, and sexually transmitted infection (STI)/human immunodeficiency virus (HIV).

2. The direct to consumer campaign will be designed to target those ages 18 to 44.
   i) The language and visuals used will be appropriate and of interest to this targeted age group. New promotional materials will be provided for comment to FDA during the development process and will be tested via market research

to ensure appropriate communication according to current practices.

ii) Media placements that target audiences age 17 years and younger will not be used.

III. Distribution

The sponsor believes that in the interest of responsible usage (and in recognition of the circumstances of the need for emergency contraception), Plan B® should be available in those retail pharmacy outlets that typically sell a broad range of OTC medications and that have pharmacy services staffed with pharmacists (or, in the case of clinics, other healthcare professionals) during normal business hours to answer questions. Since Plan B® will have a prescription only requirement for women age 17 years and younger, Duramed Pharmaceuticals and the third party distributors, wholesaler distribution and chain drug companies, will only be allowed to distribute Plan B® to licensed pharmacies or other licensed healthcare clinics, as it would be unlawful to distribute a prescription product to any business that does not have a valid pharmacy license and/or physician license. Duramed has been in contact with at least three of the largest wholesaler distributors in the country as well as some of the largest retail chain drug accounts that purchase Plan B® directly from Duramed. Each of the wholesaler distributors and chain drug companies confirmed that, since Plan B® has both Rx and OTC labeling, they will treat Plan B® as any other Rx product for distribution purposes; specifically, that it would only be distributed to licensed pharmacies or healthcare clinics. Therefore, Plan B® will not be available at gas stations or convenience stores. Additionally, since Plan B® has both Rx and OTC labeling, the pharmacies will keep the product behind the counter and control it as an Rx product. The pharmacy and clinic settings will also allow pharmacists and other healthcare providers to properly restrict OTC access to those age 18 years and older.

IV. Monitoring

The sponsor intends to monitor trends in the use of emergency contraception to evaluate the effectiveness of the CARE℠ program and will make adjustments as appropriate. Monitoring will be accomplished in several ways, with information gathered from both healthcare professionals and consumers.

Monitoring actual use of Plan B® is complex due to the difficulties inherent in identifying those who have purchased the product and in gathering useful, generalizable information. Consequently, the monitoring component will rely on a variety of sources intended to provide trend data, observational data, and signals of program effectiveness and potential problems. Monitoring components will include the following:

1. A market research survey or surveys of a subset of healthcare professionals (e.g. OB/GYN, family practice, pharmacists, nurses, family planning and health clinic personnel) annually, and when practicable, in collaboration with established professional groups e.g., National Association of Boards of Pharmacy (NABP), College of Obstetricians and Gynecologists (ACOG), American College Health Association (ACHA), National Association of Chain Drug Store (NACDS), Consumer Healthcare Products Association (CHPA), Healthcare Distribution Management Association (HDMA) to determine:

    - Whether the prescription requirement for women ages 17 and younger is understood and is being adhered to at the point of purchase
    - Attitudes toward and experience with patients' usage of Plan B®
    - Trends among emergency contraception users within their patient population (especially source of awareness, repeat use, use instead of more effective forms of contraception, incidence of STIs, etc.)

- Nature of interactions with Plan B® users (Does the contact with the healthcare professional occur prior to product usage? after usage? Are the women in search of contraceptive counseling? What types of side effects are being seen in use?)
- Areas where additional information is needed in the marketplace, as identified by the questions raised by the users

2. Using relevant survey data regularly collected by others (e.g. Centers for Disease Control's Behavioral Risk Factor Safety Surveillance (CDC BRFSS), Youth Risk Behavior Safety Surveillance (YRBSS), Foundations and Nongovernmental Organizations (NGO) surveys) the sponsor will monitor for potential indicators that Plan B® is being used in an inappropriate manner. Where existing surveys do not include relevant data, the sponsor may seek inclusion of appropriate questions. Potential areas of monitoring and reporting include:
   - Data and trends in STIs based on geographic areas;
   - Data and trends in pregnancy and/or abortion rates based on geographic areas;
   - The sponsor recognizes that the use of these sources may not give timely enough data to evaluate the CARE℠ program in the first few months of marketing. However, the commitment to monitoring extends beyond the initial stages of product introduction, and working with data sources to enhance collection of data relevant to use of Plan B® will be ongoing.
3. Gathering data from actual users of Plan B® is difficult because the number of users will be relatively small and because the decision to use emergency contraception is a private and emotional one. Women choosing to use the product are expected to wish to remain anonymous and are entitled to maintain their privacy. Nevertheless, the sponsor will work with a variety of sources in an effort to obtain and analyze consumer data in accordance with HIPAA

regulations to assess the effectiveness of the CARE^{SM} program elements.

The sponsor proposes to provide FDA a monitoring report with the available results from the above monitoring activities on a six-month interval, with submission of the report within 30 calendar days after the six-month interval date, commencing on the date of the approval ofboth the Rx and OTC versions of Plan B®.

V. Monitoring Compliance with the Prescription Age Requirement

Monitoring compliance of the Plan B® Prescription age requirement can be somewhat complex because there will be no documented information on the purchasers of Plan B® who were old enough to obtain it as an OTC product. The Sponsor intends to monitor the level of comprehension of the Prescription age requirement particularly at the pharmacy level, where the age of consumers must be assessed at the point of purchase. The following program will provide accurate information directly related to accessing compliance:

- Point of Purchase Monitoring Program:

  The Sponsor will conduct a "Point-of-Purchase Monitoring Program", which intends to track how Plan B® is being sold at the time of purchase. Due to the challenges of obtaining specific purchase data on an OTC product and respecting consumer privacy, this program will include anonymous shoppers who will be directed to visit locations where Plan B® is available and purchase the product. These transactions will be documented and analyzed to determine the level of comprehension of the Plan B® prescription age requirement and how it is handled at the point of purchase. The shoppers in this program will be 15 to 18 years old. Parental consent will be obtained for shoppers under the age of 18 years. Locations for this program will be selected based on areas where Plan B® use is high, and will be in different regions of the US to provide a national representation of the findings. These findings would provide concrete

information on how the prescription age requirement for Plan B® is being addressed at the pharmacy and if it is properly being followed. The Sponsor will use these findings to identify areas where more education on the prescription age restriction is needed and will focus their efforts on improving the level of understanding among pharmacists and the pharmacy staff. Findings from the study will be communicated to the pharmacy, and the corporate office, if appropriate, since education and retraining will be the first course of remedial action. In the case of repeat violators, the violator's State Board of Pharmacy will be notified. Results of this point of purchase program will be provided to FDA as part of the 6-month report (see Section IV – Monitoring). The Point-of-Purchase Monitoring Program will be conducted twice in the first year (6 months after product launch and 12 months after product launch). This time period will allow the Sponsor to compare findings and identify areas where improvement was made and whether additional education is needed. The program will be conducted annually after the first year.

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