Guidance for Industry

Uniform Contraceptive Labeling

Document issued on: July 23, 1998

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Obstetrics and Gynecology Devices Branch
Division of Reproductive, Abdominal, Ear, Nose and Throat, and Radiological Devices
Office of Device Evaluation

GRZAN

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Colin Pollard, HFZ-470, Obstetrics and Gynecology Devices Branch, Office of Device Evaluation, FDA, 9200 Corporate Boulevard, Rockville, Maryland, 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Colin Pollard at 240 276-4155 or colin.pollard@fda.hhs.gov.

Additional Copies

World Wide Web/CDRH home page: http://www.fda.gov/cdrh or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1251 when prompted for the document shelf number.

GRZAN

Uniform Labeling for Contraceptive Devices: Guidance to Industry

Background

This guidance provides agency recommendations for the labeling of all contraceptive devices regarding protection from pregnancy and sexually transmitted diseases. Much of this information has already been transmitted over the years to the industry in a variety of letters and guidance documents. This guidance document is an effort to bring all of these previous recommendations together into one document that will serve to encourage a uniform approach to this type of labeling information for the consumer. Where appropriate, this same information should be included in the professional labeling for these devices. It should be noted that these recommendations are the result of an intra-agency effort that involved CDRH's Office of Device Evaluation and Office of Health and Industry Programs (OHIP), as well as the Division of Reproductive and Urologic Drug Products and the Division of Over-the-Counter Drug Products in the Center for Drug Evaluation and Research. The effort was overseen by FDA's Office of Women's Health, which also provided funding for focus studies conducted by OHIP.

Protection from Pregnancy

Labeling for all contraceptive devices (including male & female condoms, diaphragms, cervical caps, intrauterine devices (IUDs), and tubal occlusion devices (TODs) should contain an easy-to-read table with the pregnancy rates associated with all methods. This table is intended to provide the device user with pregnancy rate on his/her selected contraceptive, as well as comparative information on the pregnancy rates of various other contraceptive products. The table recommended by FDA uses pregnancy rates based on data from Trussell, et al, from the 17th edition of Contraceptive Technology (1997). Using information from a series of focus studies conducted by the CDRH, FDA developed a re-formatted table (copy attached) that contains the appropriate information in an understandable form to help people appreciate the effectiveness of their contraceptive of choice with respect to the many other products available on the market.

FDA considers the communication of information on pregnancy rates to users of contraceptive devices to be essential for their safe and effective use. Therefore, all contraceptive devices should have labeling with a table like the one recommended in this guidance document. In addition, for those products requiring professional labeling, the same table should be included in an appropriate section of that labeling.

Protection from Sexually Transmitted Diseases (STDS)

In addition to inclusion of a contraceptive efficacy table in the labeling, manufacturers should include information to the user on the ability of that contraceptive device to provide protection from STDs. FDA has requested that manufacturers, depending on the type of contraceptive device, include one of the following statements in their patient/consumer labeling regarding transmission of STDs.

For intrauterine devices (IUDs), tubal occlusion devices, and natural skin condoms:

> *This product is intended to prevent pregnancy. It does not protect against HIV infection and other sexually transmitted diseases.*

For natural skin condoms, the following additional statement should be included:

> *In order to help reduce the risk of transmission of many STDs, including HIV infections (AIDS), use a latex condom.*

For latex condoms for men:

> *(On the condom wrapper/Principal display panel)*
> *If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many sexually transmitted diseases.*
>
> *(Directions For Use)*
> *If used properly, latex condoms will help to reduce the risk of transmission of HIV infection (AIDS) and many sexually transmitted diseases, including chlamydia, genital herpes, genital warts, gonorrhea, hepatitis B, and syphilis.*

GRZAN

For male condoms made from new materials:

This interim labeling is based on slippage & breakage data while a contraceptive effectiveness study is underway.

> *You may use this [insert name] condom if you or your partner are allergic to latex.*
>
> *You should know:*
>
> - *The risks of pregnancy and sexually transmitted diseases (STDs), including AIDS (HIV infection), are not known for this condom. A study is being done.*
> - *There are laboratory tests on this [blank] material. These tests show that organisms even as small as sperm and viruses like HIV cannot pass through it.*
>
> ***Latex condoms*** [boldface] *for men, if used correctly with every act of vaginal intercourse, are highly effective at preventing pregnancy, as well as STDs, including AIDS (HIV infection).*

For female condoms, the following key elements are placed on the primary package as well as the package insert:

- *Latex condoms for men are highly effective at preventing sexually transmitted diseases, including AIDS (HIV infection), if used properly.*
- *If you are not going to use a male latex condom, you can use [insert name] to help protect yourself and your partner.*
- *[Insert name] only works when you use it. Use it every time you have sex.*
- *Before you try [insert name], be sure to read the directions in the box and learn how to use it properly.*

GRZAN

For diaphragms and cervical caps:

FDA is aware of a few clinical studies of diaphragms and vaginal spermicides that look at protection from a few STDs. However, these studies are not conclusive, and no definitive statement that can be used for uniform labeling has been developed. Therefore, no claims for STD protection afforded by diaphragms or cervical caps may be made without submission of an appropriate 510(k) premarket notification or PMA supplement.

GRZAN

References

1) Memorandum to FDA's Acting Director, Office of Women's Health, May 27, 1997, on Uniform Contraceptive Effectiveness Labeling - Completion of Project.

2) Silberberg, Paula, September 1996, Report On Four Focus Groups Among Women On Their Reactions To Two Contraceptive Efficacy Table For Uniform Labeling, Office of Health and Industry Programs, Center for Devices and Radiological Health.

3) Hatcher et al., Contraceptive Technology, 17th ed., 1997, Irvington Publishers, Inc.

Pregnancy Rates for Birth Control Methods

(For One Year of Use)

The following table provides estimates of the percent of women likely to become pregnant while using a particular contraceptive method for one year. These estimates are based on a variety of studies.

"Typical Use" rates mean that the method either was *not always used correctly* or was *not used with every act of sexual intercours*e (e.g., sometimes forgot to take a birth control pill as directed and became pregnant), or was *used correctly* but *failed anyway*.

"Lowest Expected" rates mean that the method was *always used correctly* with *every act of sexual intercourse* but *failed anyway* (e.g., always took a birth control pill as directed but still became pregnant).

Method	***Typical Use Rate of Pregnancy***	***Lowest Expected Rate of Pregnancy***
Sterilization:		
Male Sterilization	0.15%	0.1%
Female Sterilization	0.5%	0.5%
Hormonal Methods:		
Implant *(Norplant® and Norplant®-2)*	0.05%	0.05%
Hormone Shot *(Depo-Provera®)*	0.3%	0.3%
Combined Pill *(Estrogen/Progestin)*	5%	0.1%
Minipill *(Progestin only)*	5%	0.5%
Intrauterine Devices (IUDs):		
Copper T	0.8%	0.6%
Progesterone T	2%	1.5%
Barrier Methods:		
Male Latex Condom [1]	14%	3%
Diaphragm [2]	20%	6%
Vaginal Sponge *(no previous births)* [3]	20%	9%
Vaginal Sponge *(previous births)* [3]	40%	20%
Cervical Cap *(no previous births)* [2]	20%	9%
Cervical Cap *(previous births)* [2]	40%	26%
Female Condom	21%	5%
Spermicide: *(gel, foam, suppository, film)*	26%	6%
Natural Methods:		
Withdrawal	19%	4%
Natural Family Planning *(calendar, temperature, cervical mucus)*	25%	1-9%
No Method:	85%	85%

[1] Used Without Spermicide

[2] Used With Spermicide

[3] Contains Spermicide

Data adapted from: Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Stewart F, et al. Contraceptive Technology: Seventeenth Revised Edition. New York, NY: Ardent Media, 1998.

Table prepared by FDA: 5/13/97, revised 9/17/98