FOR IMMEDIATE RELEASE

Contact: Amber McCasland
Porter Novelli for Mayer Laboratories
415-975-3329
amber.mccasland@porternovelli.com

MAYER LABORATORIES DISCONTINUES THE USE
OF NONOXYNOL-9 IN ITS CONDOM AND LUBRICANT PRODUCTS

Company Takes Firm, Socially Responsible Stance on Utilization of N-9
Amid Growing Concerns Regarding Public Health

OAKLAND, Calif., October 1, 2002 – Mayer Laboratories, Inc., a leading consumer reproductive healthcare products company, today announced that it has discontinued the use of nonoxynol-9 (N-9) in all of its reproductive healthcare products. This decision comes on the heels of new statements from the World Health Organization and Centers for Disease Control and Prevention urging consumers to cease the rectal use of products containing the spermicide. Still considered an effective contraceptive for unwanted pregnancies, new data suggests that N-9 provides no protection against HIV and little, if any, protection against bacterial sexually transmitted infections (STIs).

The fourth largest condom manufacturer in the United States, Mayer Labs is currently discontinuing the use of N-9 in its "Plus" line of contraceptive products. This line includes the following condom brands: Kimono® Plus, Kimono® MicroThin Plus, MAXX Plus® and Kimono® Sensation Plus. Mayer Labs is also discontinuing the use of N-9 in its Aqua Lube Plus® brand personal lubricant and is taking important steps towards the reformulation of its current base of lubricants. Mayer Labs will unveil these new, reformulated N-9 free options to consumers in early 2003.

“We're sending a strong message to our consumers and members of the industry that Mayer Laboratories is firmly committed to the safety, efficacy and reliability of all of our products," said David Mayer, president of Mayer Labs. "Our decision is in alignment with the public health studies and initiatives calling for all lubricants and condoms to be safe and effective for all forms of sexual activity. We are announcing these important actions and making these critical changes in our products to support the business of our customers and the health of all consumers."

Nonoxynol-9 kills sperm and is the active ingredient in most over-the-counter spermicidal products available in the United States and many other countries. Initially thought to be an effective microbicide against STIs and HIV, new studies show that products containing small amounts of N-9, when used rectally, can cause massive short-term disruption and shedding of epithelium cells lining the rectum. This creates an environment that may increase an individual's risk of contracting HIV or other STIs. Because these studies indicate that this product causes harm, and does not consistently provide a known benefit, Mayer Labs elected to take it out of its products.
“With these recent findings and actions, what is of equal importance, and of great concern, is that we continue to reinforce the effectiveness of condoms and the appropriateness of practicing safer sex. Condoms are still an effective form of contraception,” Mayer added. “We have made these important decisions, including a new retailer education program, in support of our dedication to social responsibility and the well-being of our consumers.”

In a recent press conference, David Mayer joined fellow industry supporters at the Planned Parenthood® Federation of America, The Global Campaign for Microbicides and the American Foundation for AIDS Research (amFAR) to discuss the study findings and collectively call for the discontinuation of N-9 in condom and lubricant products. More than 85 leading scientists and health groups have issued a statement calling for condom and lubricant manufacturers to voluntarily remove N-9 from their products.

“The belief that N-9 helps prevent HIV is deeply entrenched and it would take years and a massive public education campaign to set the record straight,” said Lori Heise, Director of the Global Campaign for Microbicides. “The most prudent thing to do is to eliminate the risk by removing N-9 from lubricants and condoms now.”

About Mayer Laboratories:
Mayer Labs is an innovative, California-based company with 16 years experience in marketing and distributing the best quality consumer healthcare products in the United States and abroad. Mayer Labs’ products include Kimono® brand condoms, eZ on® brand condoms, MAXX® brand condoms, Aqua Lube® brand personal lubricants, the FC Female Condom™ and Digitex® brand examination gloves. For more information about Mayer Laboratories, please visit www.mayerlabs.com.

###
What is Nonoxynol-9 ("N-9")?

- N-9 is a chemical in a category of compounds called “surfactants”. Surfactants work by disturbing the cell membrane.
- N-9 kills sperm and is the active ingredient in most over-the-counter ("otc") spermicidal products available in the United States and many other countries.
- Initially it was thought that N-9 was also an effective microbicide against Sexually Transmitted Infections (STIs) and HIV (AIDS). In vitro (laboratory) studies show that N-9 produces bactericidal and virucidal effects by disrupting the cell membrane and the viral envelope. But recent in vivo (in people) studies are changing the way people think.

What Products Contain Nonoxynol-9?

N-9 is found in three categories of products:

- **Condoms** - Some condoms contain N-9. All spermicidally lubricated condoms use N-9. N-9 is indicated on the front of the condom box as: “spermicidally lubricated” or “with spermicide lubrication”. Additionally, the active spermicide ingredient nonoxynol-9 will be indicated on the back of the box.

- **Personal Lubricants** - Nonoxynol-9 is also found in some personal (sexual) lubricants and will be included in the list of ingredients. Many brands use the word "Plus" to indicate they contain N-9.

- **Vaginal Contraceptives** - N-9, as a spermicide, has been the active ingredient for vaginal contraceptives since the 1930s. These spermicidal products have been on the market for decades. (eg, Conцепtro®, Delfen®, Ortho-Gynol, Encare®, VCF®, Semicid®, Advanatage®, KY® Plus, and Koromex®).

The practice of adding N-9 to personal lubricants and condoms accelerated in the late 1980’s and early 1990’s when it was widely believed, based on in vitro (laboratory) testing, that Nonoxynol-9 provided some protection, as a microbicide, against bacterial STIs and HIV, in addition to its original spermicidal role. Therefore it became a popular additive to lubricants and condoms, and it was widely recommended by public health officials.

What are the problems with Nonoxynol-9?

Most people do not have problems or increased risks when they use products which contain N-9. However, we are now learning more from in vivo (in people) studies about N-9 than from earlier in vitro (laboratory) studies. We are learning:
• that products containing small amounts of N-9, when used rectally, can cause massive short-term disruption and shedding of epithelium cells lining the rectum. This creates an environment which may increase an individual’s risk of contracting HIV or other STIs.
• that N-9 does not provide protection against STIs or HIV and may actually increase the risk of contracting HIV under certain circumstances.

Some of the problems and increased risks associated with N-9 products are:

1. Men and women who have rectal sex and put N-9 products into the rectum have an increased risk of HIV and Sexually Transmitted Infection (“STI”).
2. Women who use N-9 vaginal contraceptives during multiple acts of intercourse daily AND who are at high risk for HIV infection will be at increased risk of HIV infection.
3. Some women who use N-9 products have increased risk of bladder infections.
4. Some men and women who use N-9 products may experience:
   • burning/irritation at the opening of the urethra (where urine comes out),
   • rashes or allergic reactions, or
   • a bitter taste and numb tongue when N-9 products are put in the mouth

How large is the N-9 Condom Market:

Condoms with N-9 are generally known as “spermicidally lubricated” condoms and they continue to be a substantial part of the condom market. The total retail condom market is approximately $230 million, of that $81 million is still spermicidally lubricated condoms (IRI November 30, 2003).

Are condoms effective without N-9?

Condoms are a very effective form of contraception. If used properly and consistently, condoms, as a barrier, will help reduce the risk of transmission of HIV and many STIs.

While it has been widely believed that spermicidal lubrication on condoms provides a “back-up”, reducing the number of active sperm should the condom slip off or break before withdrawal, there is no research that proves spermicidally lubricated condoms are more effective at either contraception or STI protection than condoms with silicone oil lubricant or water-based lubricants.

Is there an alternative to N-9?

N-9 continues to be an effective and recommended contraceptive. At this time there is not an alternate FDA approved vaginal or rectal microbicide. It is vitally
important for on-going research to develop vaginal and rectal microbicides that are both safe and effective as soon as possible.

**What are current Public Health recommendations regarding use of N-9 products?**

The CDC 2002 STD Treatment Guidelines (May 3, 2002): “...N-9 can damage the cells lining the rectum, thus providing a portal of entry for HIV and other sexually transmissible agents. Therefore, N-9 should not be used as a microbicide or lubricant during anal sex.”

The CDC (May 10, 2002): “In the future, purchase of condoms lubricated with N-9 is not recommended because of their increased cost, shorter shelf life, association with urinary tract infections in young women, and lack of apparent benefit compared with other lubricated condoms.

Recent WHO (World Health Organization) consensus statement on Nonoxynol-9 (June, 2002): “There is no evidence that N-9-lubricated condoms provide any additional protection against pregnancy or STIs compared with condoms lubricated with other products. Since adverse effects due to the addition of N-9 to condoms cannot be excluded, such condoms should no longer be promoted.”

**What are the arguments against discontinuing Nonoxynol-9?**

Several manufacturers have said that they will continue to sell products containing N-9 because their customers, many of whom do not experience problems or increased risks with N-9, want those products. Whether it is real or perceived, consumers value the “back-up” role of spermicidal lubrication on condoms.

There is also a concern that any negative publicity about condoms might discourage consumers from using condoms all together.

**Where can I go to get more information on N-9?**

www.conrad.org  
www.who.int/reproductive-health/rtis/index.htm  
www.MayerLabs.com  
www.global-campaign.org  
www.cdc.gov/std/treatment/default.htm

Questions? Call 1-800-426-6366
MAYER LABORATORIES TO DESTROY 1 MILLION
SPERMICIDALLY LUBRICATED CONDOMS

Company, HIV Service Organizations Take Firm, Socially Responsible Stance
on Utilization of N-9

products company, will destroy more than one million condoms which contained nonoxynol-9 (N-9), a
common spermicidal condom lubricant that has been shown to increase risk of HIV and other sexually
transmitted infections (STIs). The condoms, at Mayer Labs' distribution center in Oakland, and at its
factory in Atsugi, Japan, are being shredded into tiny pieces to prevent any possible use.

Initially thought to be an effective microbicide against STIs and HIV, N-9 now has been shown to increase
the risk of contracting infections including HIV/AIDS. In the summer of 2002, the WHO and CDC
announced the results of new studies, and both commenced initiatives to make all condoms safe by
condoms being destroyed today are part of Mayer Labs’ inventory and returns from the marketplace.

It is important to emphasize that condoms are an important means of preventing HIV and other sexually
transmitted infections. **It is better to use a condom containing N-9 than to use no condom at all.**

The California AIDS Clearinghouse, L.A. Gay & Lesbian Center, and representatives from other state
wide organizations will join Mayer Labs to express their concerns about the continued use and sales of
spermicidally lubricated (N-9) condoms. Despite the educational efforts of many health organizations over
the past 18 months, consumers remain unaware of the risks of N-9 use. According to recent data 35.3%
of all condoms sold in drugstores, foodstores, and mass retailers were spermicidally lubricated (N-9).
Over the past year there was only a 2.2% decline in sales of spermicidally lubricated condoms (IRI:
November 5, 2003).

"We are all in a struggle to stem the spread of this horrible epidemic, and condom use is a chief weapon in
that struggle," said Dean Goishi, Director of the California AIDS Clearinghouse. "But we now know that
spermicidally lubricated condoms create an unnecessary risk of HIV infection. As long as spermicidally
lubricated condoms remain on the market, health providers and advocates face the additional burden of counteracting a confusing and dangerous message to consumers. From a moral and public health perspective, the solution is clear. Mayer Laboratories has exerted leadership by discontinuing manufacture of all condoms containing N-9. Other companies must follow that example.”

“Condoms are highly effective.” stated David Mayer, President of Mayer Laboratories, Inc. "As manufacturers, we simply need to get N-9 condoms off the market to eliminate any possible risk. So, to the makers of Trojans and Lifestyles – Stop making and distributing N-9 condoms! We are concerned that consumers are using these products not knowing the risks. We are urging our competitors to ‘do the right thing,’ " he added

In September 2002, Mayer Labs, the L.A. Gay & Lesbian Center, San Francisco AIDS Foundation and other health organizations joined Planned Parenthood® Federation of America, The Global Campaign for Microbicides and the American Foundation for AIDS Research (amFAR) to collectively call for the discontinuation of N-9 in condom and lubricant products. More than 85 leading scientists and health groups have issued a statement calling for condom and lubricant manufacturers to voluntarily remove N-9 from their products.

**About Mayer Laboratories:**
Mayer Labs is an innovative, California-based company with 17 years experience in marketing and distributing the best quality consumer healthcare products in the United States and abroad. Mayer Labs’ products include Kimono® brand condoms, eZ•on® brand condoms, MAXX® brand condoms, Aqua Lube® brand personal lubricants, FC Female Condom™ and Digix® brand examination gloves. For more information about Mayer Laboratories, please visit [www.mayerlabs.com](http://www.mayerlabs.com).

**About the California AIDS Clearinghouse:**
The California AIDS Clearinghouse (CAC) provides appropriate and culturally sensitive technical assistance, educational materials, and support services to Education & Prevention Programs and Test Sites funded by the State of California, Department of Health Services, Office of AIDS and non-profit organizations throughout California. The Clearinghouse takes a leadership role in developing a direct partnership with education and prevention and HIV Testing Programs in order to create support services and educational materials that are culturally sensitive, language appropriate, and meet the educational needs of these programs. In addition, the Clearinghouse has the responsibility of promoting understanding, communication, and involvement among all members of the community, to improve the quality of HIV/AIDS educational materials. For more information about CAC please visit [www.hivinfo.org/](http://www.hivinfo.org/)

###