

Prostitutes," *Sexually Transmitted Diseases*, 24(5):279-283, 1997.

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28. Rustomjee, R. et al., "Phase 1 Trial of Nonoxynol 9 Film Among Sex Workers in South Africa," *AIDS*, 13:1511-1515, 1999.

29. CDC, "Nonoxynol-9 Spermicide Contraception Use—United States, 1999," *Morbidity and Mortality Weekly Report*, 51(18): 389-392, 2002.

30. WHO, "Nonoxynol-9 Ineffective in Preventing HIV Infection," May 28, 2002.

31. WHO, "WHO/CONRAD Technical Consultation on Nonoxynol-9, Summary Report," 2001.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 201 be amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360b, 360gg-360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Section 201.66 is amended by adding paragraph (c)(5)(ii)(H) to read as follows:

§ 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.

* * * * *

(c) * * *

(5) * * *

(ii) * * *

(H) Sexually transmitted diseases (STDs) warning for vaginal contraceptive drug products containing nonoxynol 9 set forth in § 201.325(b)(2). This warning shall follow the subheading "Sexually transmitted diseases (STDs) alert:"

3. Section 201.325 is added to subpart G to read as follows:

§ 201.325 Over-the-counter drugs for vaginal contraceptive use containing nonoxynol 9 as the active ingredient; required warnings.

(a) Studies indicate that use of vaginal contraceptives containing nonoxynol 9 does not protect against infection from the human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome (AIDS), or against the transmission of other

sexually transmitted diseases (STDs). Studies also suggest that frequent use of vaginal contraceptives containing nonoxynol 9 can increase vaginal irritation, such as the disruption of the vaginal epithelium. These effects may increase the risk of transmission of the AIDS virus (HIV) and other STDs from an infected partner. Consumers should be warned that these products do not protect against the transmission of the AIDS virus (HIV) or other STDs. In addition, frequent use of these products can increase vaginal irritation, which may increase the risk of getting certain STDs, including the AIDS virus (HIV), from infected partners.

(b) The labeling of OTC vaginal contraceptive drug products containing nonoxynol 9 as the active ingredient, whether subject to the ongoing OTC drug review or an approved drug application, must contain the following warnings under the heading "Warnings," in accordance with § 201.66.

(1) "For vaginal use only" [this heading in bold type]

(2) "Sexually transmitted diseases (STDs) alert [this heading in bold type]: This product does not [this word in bold type] protect against the AIDS virus (HIV) or other STDs."

(3) "Ask a doctor before use if you have [heading in bold type] [optional, bullet] a new sex partner, multiple sex partners, or unprotected sex. Frequent use (more than once a day) of this product can increase vaginal irritation, which may increase the risk of getting the AIDS virus (HIV) or other STDs from infected partners. Ask a doctor or other health professional for your best birth control method."

(4) "Stop use and ask a doctor if [heading in bold type] [optional, bullet] you or your partner get burning, itching, a rash, or other irritation of the vagina or penis"

(c) The labeling of this product must include the following statements either on the outside container or wrapper of the retail package, under the "Other information" section of the Drug Facts labeling in accordance with § 201.66(c)(7), or in a package insert.

(1) "[Bullet] Studies have raised safety concerns that frequent use (more than once a day) of products containing nonoxynol 9 can increase vaginal irritation, which may increase the risk of getting the AIDS virus (HIV) or other STDs from infected partners. Vaginal irritation may include symptoms such as burning, itching, or a rash, or you may not notice any symptoms at all. If you use these products frequently and/or have a new sex partner, multiple sex partners, or unprotected sex, see a

doctor or other health professional for your best birth control and methods to prevent STDs."

(2) "[Bullet] Correct use of a latex condom with every sexual act will help reduce the risk of getting the AIDS virus (HIV) and other STDs from infected partners."

(d) Any drug product subject to this section that is not labeled as required and that is initially introduced or initially delivered for introduction into interstate commerce after [date 6 months after date of publication of the final rule in the **Federal Register**], is misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352), is a new drug under section 505 of the act (21 U.S.C. 355), and is subject to regulatory action.

Dated: December 19, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[Notice No. 966; re: Notice Nos. 960 and 961]

RIN 1512-AC76 and 1512-AC66

Red Hill (Oregon) Viticultural Area (2001R-88P); Red Hills (California) Viticultural Area (2001R-330P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Notices of proposed rulemaking (NPRMs); reopening of comment periods.

SUMMARY: We are reopening the comment periods for NPRMs No. 960 and No. 961. Both NPRMs were published in the **Federal Register** on October 30, 2002. The proposed rules, if approved, would add Red Hill (Oregon) and Red Hills (California) as approved American viticultural areas and amend 27 CFR part 9. We are acting on a request to extend the comment period in order to provide sufficient time for all interested parties to respond to the issues raised in the notice.

DATES: Written comments must be received on or before March 17, 2003.

ADDRESSES: You may send comments to any of the following addresses:

- Chief, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 50221, Washington, DC 20091-0221