

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

26. Roddy, R. E. et al., "A Controlled Trial of Nonoxynol 9 Film to Reduce Male-to-Female Transmission of Sexually Transmitted Diseases," *New England Journal of Medicine*, 339(8):504-510, 1998.

27. Van Damme, L. V. et al., "Safety of Multiple Daily Applications of COL-1492, A Nonoxynol-9 Vaginal Gel, Among Female Sex Workers," *AIDS* 2000, 14(1):85-88, 2000.

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.

[FR Doc. 03-902 Filed 1-15-03; 8:45 am]

BILLING CODE 4160-01-S

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

(Attn: Notice No. 960 or Attn: Notice No. 961);

- 202-927-8525 (facsimile);
- nprm@atfhq.atf.treas.gov (e-mail);
- <http://www.atf.treas.gov> (online).

A comment form is available with each of the online copies of these notices. At this site, select "Regulations," then "Notices of proposed rulemaking (Alcohol)." Finally, select "Send comments via e-mail" under the appropriate notice number.

You may view copies of the NPRMs, the request for extension, and any comments received on the notices by appointment at the ATF Reference Library, Room 6480, 650 Massachusetts Avenue, NW., Washington, DC 20226, or at <http://www.atf.treas.gov> with an online copy of Notice No. 960 and/or Notice No. 961.

FOR FURTHER INFORMATION CONTACT: Tim DeVanney, Regulations Division, Bureau of Alcohol, Tobacco & Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226; telephone 202-927-8210; e-mail TPDevanney@atfhq.atf.treas.gov.

SUPPLEMENTARY INFORMATION:

Background

On October 30, 2002, ATF published two NPRMs (Notice No. 960, 67 FR 66079, and Notice No. 961, 67 FR 66083) to establish Red Hill (Oregon) and Red Hills (California), respectively, as American viticultural areas. The comment periods ended on December 30, 2002. Before the close of the comment periods, ATF received a request from Mr. Sean Carlton of Archery Summit, a winery in Dayton, Oregon, to extend the comment periods for an additional 60 days. Mr. Carlton requested the extension to allow more time to study the petitions and research the respective areas.

In consideration of the above, we find that a reopening of the comment periods is warranted.

Public Participation

See the Public Participation section of either Notice No. 960, or Notice No. 961 for detailed instructions on submitting and reviewing comments. Comments received on or before the new closing dates will be carefully considered.

We will not recognize any submitted material as confidential, and comments may be disclosed to the public. Any material that the commenter considers confidential or inappropriate for disclosure to the public should not be included in the comments. The name of the person submitting a comment is not exempt from disclosure.

Drafting Information

Tim DeVanney of the Regulations Division, Bureau of Alcohol, Tobacco and Firearms, drafted this notice.

List of Subjects in 27 CFR Part 9

Wine.

Authority and Issuance

Both Notice No. 960 and Notice No. 961 were issued under the authority of 27 U.S.C. 205.

Signed: January 8, 2003.

Bradley A. Buckles,

Director.

[FR Doc. 03-847 Filed 1-15-03; 8:45 am]

BILLING CODE 4810-31-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 901

[AL-072-FOR]

Alabama Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are announcing receipt of a proposed amendment to the Alabama regulatory program (Alabama program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Alabama proposes revisions to its rules about forms and license applications. Alabama intends to revise its program to improve operational efficiency.

This document gives the times and locations that the Alabama program and proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: We will accept written comments on this amendment until 4 p.m., c.s.t., February 18, 2003. If requested, we will hold a public hearing on the amendment on February 10, 2003. We will accept requests to speak at a hearing until 4 p.m., c.s.t. on January 31, 2003.

ADDRESSES: You should mail or hand deliver written comments and requests to speak at the hearing to Arthur W.

Abbs, Director, Birmingham Field Office, at the address listed below.

You may review copies of the Alabama program, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Birmingham Field Office.

Arthur W. Abbs, Director, Birmingham Field Office, Office of Surface Mining Reclamation and Enforcement, 135 Gemini Circle, Suite 215, Homewood, Alabama 35209. Telephone: (205) 290-7282. Internet: aabbs@osmre.gov.

Alabama Surface Mining Commission, 1811 Second Avenue, P.O. Box 2390, Jasper, Alabama 35502-2390. Telephone: (205) 221-4130.

FOR FURTHER INFORMATION CONTACT: Arthur W. Abbs, Director, Birmingham Field Office. Telephone: (205) 290-7282. Internet: aabbs@osmre.gov.

SUPPLEMENTARY INFORMATION:

- I. Background on the Alabama Program
- II. Description of the Proposed Amendment
- III. Public Comment Procedures
- IV. Procedural Determinations

I. Background on the Alabama Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, "a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act." See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Alabama program on May 20, 1982. You can find background information on the Alabama program, including the Secretary's findings, the disposition of comments, and the conditions of approval in the May 20, 1982, **Federal Register** (47 FR 22030). You can also find later actions concerning the Alabama program and program amendments at 30 CFR 901.10, 901.15, and 901.16.

II. Description of the Proposed Amendment

By letter dated October 17, 2002 (Administrative Record No. AL-0654),