

of Food and Drugs, it is proposed that 21 CFR parts 310 and 358 be amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

2. Section 310.545 is amended by revising paragraph (d)(3) to read as follows:

§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

* * * * *

(d) * * *

(3) December 4, 1992, for products subject to paragraph (a)(7) of this section that contain menthol as an antipruritic in combination with the antidandruff ingredient coal tar identified in § 358.710(a)(1) of this chapter. This section does not apply to products allowed by § 358.720(b) of this chapter after January 9, 2006.

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PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

3. The authority citation for 21 CFR part 358 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

4. Section 358.720 is revised to read as follows:

§ 358.720 Permitted combinations of active ingredients.

(a) *Combination of active ingredients for the control of dandruff.* Salicylic acid identified in § 358.710(a)(4) may be combined with sulfur identified in § 358.710(a)(6) provided each ingredient is present within the established concentration and the product is labeled according to § 358.750.

(b) *Combination of control of dandruff and external analgesic active ingredients.* Coal tar identified in § 358.710(a)(1) may be used at a concentration of 1.8 percent coal tar solution, on a weight-to-volume basis, in combination with menthol, 1.5 percent, in a shampoo formulation provided the product is labeled according to § 358.760.

5. New § 358.760 is added to subpart H to read as follows:

§ 358.760 Labeling of permitted combinations of active ingredients for the control of dandruff.

The statement of identity, indications, warnings, and directions for use,

respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(1) *Combinations of control of dandruff and external analgesic active ingredients in § 358.720(b).* The label states “dandruff/anti-itch shampoo” or “antidandruff/anti-itch shampoo”.

(2) [Reserved]

(b) *Indications.* The labeling of the product states, under the heading “Uses,” one or more of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing only the uses that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *Combinations of control of dandruff and external analgesic active ingredients in § 358.720(b).* The labeling states “[bullet] [select one of the following: ‘for relief of’ or ‘controls’] the symptoms of dandruff [bullet] [select one of the following: ‘additional’ or ‘extra’] relief of itching due to dandruff”.

(2) The following terms or phrases may be used in place of or in addition to the words “for relief of” or “controls” in the indications in paragraph (b)(1) of this section: “fights,” “reduces,” “helps eliminate,” “helps stop,” “controls recurrence of,” “fights recurrence of,” “helps prevent recurrence of,” “reduces recurrence of,” “helps eliminate recurrence of,” “helps stop recurrence of”.

(3) The following terms may be used in place of the words “the symptoms of” in the indication in paragraph (b)(1) of this section: “scalp” (select one or more of the following: “itching,” “irritation,” “redness,” “flaking,” “scaling”) “associated with”.

(c) *Warnings.* The labeling of the product states, under the heading “Warnings,” the warning(s) listed in § 358.750(c)(1) and (c)(2).

(d) *Directions.* The labeling of the product states, under the heading “Directions,” directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph (d). When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not contain any dosage that exceeds those established for any individual ingredient in the applicable OTC drug monograph(s), and may not provide for use by any age group lower than the highest minimum age limit established for any individual ingredient.

(1) *Combinations of control of dandruff and external analgesic active ingredients in § 358.720(b).* The labeling states “[bullet] wet hair [bullet] apply shampoo and work into a lather [bullet] rinse thoroughly [bullet] for best results, use at least twice a week or as directed by a doctor”.

(2) [Reserved]

Dated: December 5, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23839 Filed 12–8–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 635

RIN 0702-AA52-U

Law Enforcement Reporting

AGENCY: Department of the Army, DoD.

ACTION: Proposed rule.

SUMMARY: The Department of the Army proposes to amend its regulation concerning law enforcement reporting, to implement portions of section 577(b)(5) of the Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005, October 28, 2004, Pub. L. 108–375, pertaining to reporting of sexual assaults. This revision also implements Department of Defense policy concerning sexual assault.

DATES: Comments submitted to the address below on or before January 9, 2006 will be considered.

ADDRESSES: You may submit comments, identified by “32 CFR Part 635 and RIN

0702-AA52-U in the subject line, by any of the following methods:

- *Federal Rulemaking Portal*: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-Mail*:

Nathan.evans3@us.army.mil. Include 32 CFR Part 635 and RIN 0702-AA52-U in the subject line of the message.

- *Mail*: Headquarters, Department of the Army, Office of the Provost Marshal General, ATTN: DAPM-MPD-LE, 2800 Army Pentagon, Washington, DC 20310-2800.

FOR FURTHER INFORMATION CONTACT:

Nathan Evans, Policy Analyst, Arlington, VA at (703) 693-2126.

SUPPLEMENTARY INFORMATION:

A. Background

This rule has previously been published. The Department of Defense and the Department of the Army have implemented policies concerning sexual assault that affect law enforcement reporting. The Administrative Procedure Act, as amended by the Freedom of Information Act, requires that certain policies and procedures and other information concerning the Department of the Army be published in the **Federal Register**. The policies and procedures covered by this part fall into that category.

B. Regulatory Flexibility Act

The Department of the Army has determined that the Regulatory Flexibility Act does not apply because the proposed rule does not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601-612.

C. Unfunded Mandates Reform Act

The Department of the Army has determined that the Unfunded Mandates Reform Act does not apply because the proposed rule does not include a mandate that may result in estimated costs to State, local or tribal governments in the aggregate, or the private sector, of \$100 million or more.

D. National Environmental Policy Act

The Department of the Army has determined that the National Environmental Policy Act does not apply because the proposed rule does not have an adverse impact on the environment.

E. Paperwork Reduction Act

The Department of the Army has determined that the Paperwork Reduction Act does not apply because the proposed rule does not involve

collection of information from the public.

F. Executive Order 12630 (Government Actions and Interference With Constitutionally Protected Property Rights)

The Department of the Army has determined that Executive Order 12630 does not apply because the proposed rule does not impair private property rights.

G. Executive Order 12866 (Regulatory Planning and Review)

The Department of the Army has determined that according to the criteria defined in Executive Order 12866 this proposed rule is not a significant regulatory action. As such, the proposed rule is not subject to Office of Management and Budget review under section 6(a)(3) of the Executive Order.

H. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)

The Department of the Army has determined that according to the criteria defined in Executive Order 13045 this proposed rule does not apply.

I. Executive Order 13132 (Federalism)

The Department of the Army has determined that according to the criteria defined in Executive Order 13132 this proposed rule does not apply because it will not have a substantial effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Jeffery B. Porter

Chief, Law Enforcement Policy and Oversight Section.

List of Subjects in 32 CFR Part 635

Crime, Law, Law enforcement, Law enforcement officers, Military law.

For reasons stated in the preamble the Department of the Army proposes to amend 32 CFR Part 635 to read as follows:

PART 635—LAW ENFORCEMENT REPORTING

1. The authority citation for part 635 continues to read as follows:

Authority: 28 U.S.C. 534 note, 42 U.S.C. 10601, 18 U.S.C. 922, 42 U.S.C. 14071, 10 U.S.C. 1562, 10 U.S.C. Chap. 47, Pub. L. 108-375.

§§ 635.31 and 635.32 [Redesignated as §§ 635.32 and 635.33]

2. Redesignate §§ 635.31 and 635.32 as §§ 635.32 and 635.33, respectively.

§§ 635.33 through 653.36 [Redesignated as §§ 635.34 through 635.37]

3. Redesignate §§ 635.33 through 635.36 as §§ 635.34 through 635.37, respectively.

4. A new § 635.31 is added to Subpart D to read as follows:

§ 635.31 Procedures for Restricted/Unrestricted Reporting in Sexual Assault Cases.

Active duty Soldiers, and Army National Guard and U.S. Army Reserve Soldiers who are subject to military jurisdiction under the UCMJ, can elect either restricted or unrestricted reporting if they are the victim of a sexual assault.

(a) Unrestricted Reporting. Unrestricted reporting requires normal law enforcement reporting and investigative procedures.

(b) Restricted reporting requires that law enforcement and criminal investigative organizations not be informed of a victim's identity and not initiate investigative procedures. The victim may allow Sexual Assault Response Coordinators (SARC), medical treatment facility personnel, or chaplains to collect specific items (clothing, bedding, etc.) that may be later used as evidence, should they decide to later report the incident to law enforcement. In sexual assault cases additional forensic evidence may be collected using the "Sexual Assault Evidence Collection Kit," NSN 6640-01-423-9132, or a suitable substitute (hereafter, "evidence kit"). The evidence kit, other items such as clothing or bedding sheets, and any other articles provided by the Medical Treatment Facility, SARC, or chaplain will be stored in the installation provost marshal's evidence room separate from other evidence and property. Procedures for handling evidence specified in AR 195-5, Evidence Procedures, will be strictly followed.

(c) Installation Provost Marshals will complete an information report in COPS for restricted reporting. Reports will be completed utilizing the offense code from the 6Z series. An entry will be made in the journal when the sexual assault evidence kit or property (clothing, bedding, etc.) is received. An entry will not be made in the blotter. Restricted reporting incidents are not reportable as Serious Incident Reports. Property will be stored for one year and then scheduled/suspended for destruction, unless earlier released to investigative authorities. Thirty days prior to destruction of the property, a letter will be sent to the SARC by the Provost Marshal, advising the SARC that the property will be destroyed in thirty

days, unless law enforcement personnel are notified by the SARC that the victim has elected unrestricted reporting. Clothing or other personal effects may be released to the SARC for return to the victim. The information report will be updated when the evidence is destroyed, or released to investigative authorities.

(d) In the event that information about a sexual assault that was made under restricted reporting is disclosed to the commander from a source independent of the restricted reporting avenues, or to law enforcement from other sources, the commander may report the matter to law enforcement and law enforcement remains authorized to initiate its own independent investigation of the matter presented. Additionally, a victim's disclosure of his/her sexual assault to persons outside the protective sphere of the persons covered by the restricted reporting policy may result in an investigation of the allegations.

[FR Doc. 05-23853 Filed 12-8-05; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 61 and 63

[R06-OAR-2005-NM-0005; FRL-8006-3]

Approval of the Clean Air Act Section 112(I) Program for Hazardous Air Pollutants and Delegation of Authority to the Albuquerque-Bernalillo County Air Quality Control Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Albuquerque-Bernalillo County Air Quality Control Board (ABCAQCB) has submitted updated regulations for receiving delegation of EPA authority for implementation and enforcement of National Emission Standards for Hazardous Air Pollutants (NESHAPs) for all sources (both part 70 and non-part 70 sources). These regulations apply to certain NESHAPs promulgated by EPA, as amended through July 1, 2004. The delegation of authority under this action does not apply to sources in Indian Country. EPA is providing notice proposing to approve the delegation of certain NESHAPs to ABCAQCB.

DATES: Written comments must be received by January 9, 2006.

ADDRESSES: Comments may be mailed to Mr. Jeff Robinson, Air Permits Section (6PD-R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200,

Dallas, Texas 75202-2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the Addresses section of the direct final rule located in the final rules section of the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Mr. Jeff Robinson, Air Permits Section, Multimedia Planning and Permitting Division (6PD-R), U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733, at (214) 665-6435, or at robinson.jeffrey@epa.gov.

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, EPA is approving ABCAQCB's request for delegation of authority to implement and enforce certain NESHAPs for all sources (both part 70 and non-part 70 sources). ABCAQCB has adopted certain NESHAPs into state regulations. In addition, EPA is waiving its notification requirements so sources will only need to send notifications and reports to ABCAQCB.

The EPA is taking direct final action without prior proposal because EPA views this as a noncontroversial action and anticipates no adverse comments. A detailed rationale for this approval is set forth in the preamble to the direct final rule. If no adverse comments are received in response to this action rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn, and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is published in the Rules section of this **Federal Register**.

Authority: 42 U.S.C. 7412.

Dated: November 29, 2005.

Carl E. Edlund,

Acting Regional Administrator, Region 6.

[FR Doc. 05-23809 Filed 12-8-05; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[R08-OAR-2005-SD-0002; FRL-8005-1]

Designation of Areas for Air Quality Planning Purposes; State of South Dakota; Approval of Redesignation Request

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a September 30, 2005 request from the designee of the Governor of South Dakota to redesignate the "Rapid City Area" under section 107 of the Clean Air Act (CAA) from unclassifiable to attainment for PM-10. EPA is proposing to approve the redesignation request because the State has adequately demonstrated that the "Rapid City Area" is in attainment of the PM-10 National Ambient Air Quality Standards (NAAQS) and has committed to the continuation of fugitive dust controls that should help ensure that the area continues to attain the PM-10 NAAQS. The requirements that will apply in the "Rapid City Area" will not change as a result of this action because, for the purposes of the requirements of the CAA, unclassifiable and attainment areas are treated the same. This action is being taken under section 107 of the Clean Air Act.

DATES: Comments must be received on or before January 9, 2006.

ADDRESSES: Submit your comments, identified by Docket ID No. R08-OAR-2005-SD-0002, by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- Agency Web site: <http://docket.epa.gov/rmepub/index.jsp>. Regional Materials in EDOCKET (RME), EPA's electronic public docket and comment system for regional actions, is EPA's preferred method for receiving comments. Follow the on-line instructions for submitting comments.

- E-mail: long.richard@epa.gov and dygowski.laurel@epa.gov.

- Fax: (303) 312-6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).

- Mail: Richard R. Long, Director, Air and Radiation Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P-AR, 999 18th Street, Suite 200, Denver, Colorado 80202-2466.

- Hand Delivery: Richard R. Long, Director, Air and Radiation Program,