

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

The agency has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Request for Comments

This comment period runs concurrently with the comment period for the direct final rule; any comments received will be considered as comments regarding the direct final rule. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or three hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. In the event the direct final rule is withdrawn, all comments received will be considered comments on this proposed rule.

List of Subjects in 21 CFR Part 347

Labeling, Over-the-counter drugs.

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 347 be amended to read as follows:

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 347 continues to read as follows:

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

2. Section 347.52 is amended by adding paragraphs (c)(4) and (e) and by revising paragraphs (d)(1)(i), (d)(1)(ii), and (d)(3) to read as follows:

§ 347.52 Labeling of astringent drug products.

* * * * *

(c) * * *

(4) *For products containing aluminum acetate identified in § 347.12(a) when labeled for use as a soak, compress, or wet dressing.* "When using this product [bullet] in some skin conditions, soaking too long may overdry".

(d) * * *

(1) * * *—(i) *For products used as a soak.* "For use as a soak: [bullet] soak affected area for 15 to 30 minutes as needed, or as directed by a doctor [bullet] repeat 3 times a day or as directed by a doctor [bullet] discard solution after each use".

(ii) *For products used as a compress or wet dressing.* "For use as a compress or wet dressing: [bullet] soak a clean, soft cloth in the solution [bullet] apply cloth loosely to affected area for 15 to 30 minutes [bullet] repeat as needed or as directed by a doctor [bullet] discard solution after each use".

* * * * *

(3) *For products containing witch hazel identified in § 347.12(c).* "Apply as often as needed".

(e) *Products formulated and labeled as a styptic pencil and that meet the criteria established in § 201.66(d)(10) of this chapter.* The title, headings, subheadings, and information described in § 201.66(c) of this chapter shall be printed in accordance with the following specifications:

(1) The labeling shall meet the requirements of § 201.66(c) of this chapter except that the headings and information described in § 201.66(c)(3) and (c)(7) may be omitted, and the headings, subheadings, and information described in § 201.66(c)(4) and (c)(5) may be presented as follows:

(i) The heading and indication required by § 201.66(c)(4) of this chapter may be limited to: "Use [in bold type] stops bleeding of minor cuts from shaving".

(ii) The "external use only" warning in § 347.52(c)(1) and in § 201.66(c)(5)(i) of this chapter may be omitted. The second warning in § 347.52(c)(1) may state: "Avoid contact with eyes". The warning in § 201.66(c)(5)(x) may be limited to the following: "Keep out of reach of children." The subheadings in § 201.66(c)(5)(iii) through (c)(5)(vii) may be omitted, provided the information

after the heading "Warning" contains the warnings in this paragraph.

(2) The labeling shall be printed in accordance with the requirements of § 201.66(d) of this chapter, except that any requirements related to § 201.66(c)(3) and (c)(7) and the horizontal barlines and hairlines described in § 201.66(d)(8), may be omitted.

Dated: May 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–14819 Filed 6–12–03; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[FRL–7511–5]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants: Louisiana, New Mexico, Oklahoma and Bernalillo County, NM; Negative Declarations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve negative declarations submitted by the States of Louisiana, New Mexico, Oklahoma, and the City of Albuquerque (Bernalillo County), New Mexico, which certify that there are no existing small municipal waste combustion units in Louisiana, New Mexico, and Oklahoma subject to the requirements of sections 111(d) and 129 of the Clean Air Act (CAA). EPA is also proposing to approve negative declarations submitted by the State of New Mexico and the City of Albuquerque (Bernalillo County) which certify that there are no existing hospital/medical/infectious waste incinerators subject to the requirements of sections 111(d) and 129 of the CAA. In addition, EPA is proposing to approve a negative declaration submitted by the City of Albuquerque (Bernalillo County) which certifies that there are no existing large municipal waste combustion units subject to the requirements of sections 111(d) and 129 of the CAA. Finally, EPA is proposing to approve a negative declaration submitted by the State of New Mexico which certifies that there are no existing commercial and industrial solid waste incineration units subject to the requirements of sections 111(d) and 129 of the CAA.

DATES: Written comments must be received by July 14, 2003.

ADDRESSES: Written comments should be addressed to Mr. Thomas H. Diggs, Chief, Air Planning Section (6PD-L), at the EPA Region 6 Office listed below. Copies of documents relevant to this action are available for public inspection during normal business hours at the following location. Anyone wanting to examine these documents should make an appointment with the EPA Region 6 Office.

Environmental Protection Agency,
1445 Ross Avenue, Suite 700, Dallas,
Texas 75202-2733.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth W. Boyce, Air Planning Section (6PD-L), Multimedia Planning and Permitting Division, U.S. EPA, Region 6, 1445 Ross Avenue, Dallas, Texas 75202, (214) 665-7259.

SUPPLEMENTARY INFORMATION: In the "Rules and Regulations" section of this **Federal Register**, EPA is approving the submittals as a direct final rule without prior proposal because EPA views this as a noncontroversial revision and anticipates no adverse comment. The EPA has explained its reasons for this approval in the preamble to the direct final rule. If EPA receives no relevant adverse comment, EPA will not take further action on this proposed rule. If EPA receives relevant adverse comment, EPA will withdraw the direct final rule and it will not take effect. The EPA will address all public comments in a subsequent final rule based on this proposed rule. The 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 located in the "Rules and Regulations" section of this **Federal Register**.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: May 16, 2003.

Lawrence E. Starfield,

Deputy Regional Administrator, Region 6.

[FR Doc. 03-15008 Filed 6-12-03; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2003-0182; FRL-7309-7]

Humates; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Agency is proposing, on its own initiative, to amend the existing tolerance exemption for humic acid, sodium salt to include humic acid, potassium salt and humic acid. Such humate materials would be used as inert ingredients in pesticide formulations applied to growing crops under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: Comments, identified by docket ID number OPP-2003-0182, must be received on or before July 14, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Kerry Leifer, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8811; fax number: (703) 305-0599; e-mail address: leifer.kerry@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System

(NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0182. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "Federal Register" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in