

## 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 In the event the direct final rule is withdrawn, all comments received will be considered comments on this proposed rule.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.