

determining how to state the product's labeling.

The agency believes that relabeling costs of the type required by this direct final rule generally average about \$2,000 to \$3,000 per stock keeping unit (SKU) (individual products, packages, and sizes). Assuming that there are about 25 affected OTC SKU's in the marketplace, total one-time costs of relabeling would be \$50,000 to \$75,000. The agency believes that the actual cost could be lower for the reasons stated in the previous paragraph.

For the reasons stated previously and under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner certifies that this direct final rule will not have a significant economic impact on a substantial number of small entities.

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. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Comments

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.

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, 21 CFR part 347 is 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".

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(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.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[DEA-236S]

Schedules of Controlled Substances: Exempt Anabolic Steroid Products

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Suspension of interim rule.

SUMMARY: The DEA is suspending the order published January 15, 2003 designating two pharmaceutical preparations as exempt anabolic steroid products under the Controlled Substances Act (CSA). This suspension was brought about by the receipt of two