

wish to add additional indications included in this final monograph can do so at their next regular printing of product labeling. Among the steps the agency is taking to minimize the impact on small entities are: (1) To provide enough time to enable entities to use up existing labeling stock, and (2) to allow the labeling changes required by this final monograph to be done concurrently with the changes required by the new OTC drug labeling format. The agency believes that these actions provide small entities substantial flexibility and reductions in cost.

The agency considered but rejected several labeling alternatives: (1) A shorter or longer implementation period, and (2) an exemption from coverage for small entities. While the agency believes that consumers would benefit from having this new labeling in place as soon as possible, a longer time period would unnecessarily delay the benefit of new labeling and a few revised formulations. Conversely, a shorter time period was also considered but rejected because it would be inflexible and more costly for the affected companies. The agency rejected an exemption for small entities because the new labeling and revised formulations, where applicable, are also needed by consumers who purchase products marketed by those entities. However, a longer (24-month) compliance date is being provided for products with annual sales less than \$25,000.

One small manufacturer has indicated that it will suffer economic consequences because it will no longer be able to make claims for use of its antiperspirant products on the hands, and for prosthesis and orthotic use. However, the manufacturer did not provide sufficient data to show that its products were safe and effective for these uses and did not provide documentation to show the economic impact of this final rule on its sales. The agency notes that the company could: (1) Relabel its products to contain only the monograph indications and then remain in the marketplace, or (2) discontinue its products. While revising the product labeling may have an economic impact on a company, it will be able to continue to market its products and can use the expanded indications provided by the final monograph to try to enhance product sales.

The final rule would not require any new reporting and recordkeeping activities, and no additional professional skills are needed. There are no other Federal rules that duplicate, overlap, or conflict with the final rule.

For the reasons in this section and under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. 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)).

VIII. 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.

IX. Federalism

FDA has analyzed this 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.

X. Section 369.20 Revision

Section 369.20 (21 CFR 369.20) contains a recommended warning and caution statement for OTC antiperspirant drug products under the heading "ANTIPERSPIRANTS:" "Do not apply to broken skin. If a rash develops, discontinue use." This statement is very similar to, but not quite as extensive as, the warnings required by the final monograph: "Do not use on broken skin" and "Stop use if rash or irritation occurs". The agency is removing the entry for "ANTIPERSPIRANTS" under § 369.20

because it is superseded by §§ 350.50(c)(1) and (c)(2).

XI. References

The following references are on display in the Dockets Management Branch (see section I of this document) under Docket No. 78N-0064 unless otherwise stated and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum of telephone conversation between R. Bolger, C. Holland, and K. Holland, Perspi-Cura Co., and V. Miguele, FDA, in OTC vol. 1400FR, dated November 20, 1995.

2. Memorandum of fax from V. Miguele, FDA, to R. Bolger and C. Holland, Perspi-Cura Co., in OTC Vol. 1400FR, dated February 8, 1996.

3. Memorandum of telephone message from R. Bolger, Perspi-Cura Co., to V. Miguele, FDA, in OTC Vol. 1400FR, dated March 25, 1996.

4. Studies 83-0768-70 and 83-0769-70 in Comment RPT.

5. Studies S-1367, S-1617, and ST-2280/2376) in Comment No. C00039.

6. "Antiperspirant Efficacy Study of AP10016 (Currently Marketed Roll-on Antiperspirant With Aluminum Zirconium Tetrachlorohydrate) Against AP10021 (Currently Marketed Roll-on Antiperspirant With Aluminum Chlorohydrate)," Exhibit 24 in Comment No. C00040.

7. Comment No. LET006.

8. Majors, P. A., and F. B. Carabello, "Presentation to the OTC Panel for Antiperspirants of the Hill Top Research Method of Antiperspirant Evaluations and General Discussion of Results Obtained," in OTC Vol. 140065, August 1975.

9. FDA, "Guidelines for Effectiveness Testing of OTC Antiperspirant Drug Products," in OTC Vol. 140065, August 1982.

10. Exhibits 1 through 7 in Comment No. C00040.

11. "Claim for 'Twenty Four Hour Protection' etc., Antiperspirant Tests," studies S-825, S-1434, S-1473, S-1518, S-1546, and S-1604, in Comment No. C00039.

12. Exhibits 9 through 20 and 22, in Comment No. C00040.

13. Majors, P. A., and J. E. Wild, "The Evaluation of Antiperspirant Efficacy—Influence of Certain Variables," *Journal of the Society of Cosmetic Chemists*, 25:139-152, 1974.

14. "New Data on Pedal Antiperspirant Activity," studies in Comment C00041.

15. *Pedal Antiperspirant Efficacy Evaluation*, protocol in Comments PR1 and PR2.

16. Letter from W. E. Gilbertson, FDA, to K. R. Johannes, Scholl, Inc., coded LET11.

17. Letters from W. E. Gilbertson, FDA, to R. C. Stites, Numark Laboratories, Inc., coded LET12 and LET13.

18. "Protocol for the Clinical Evaluation of Antiperspirant Efficacy Against Thermally Induced Sweating," exhibit 21, in Comment No. C00040.

19. Study 83-0769-70 in Comment No. RPT.

20. "Claim for 'Twenty Four Hour Protection' etc., Antiperspirant Tests,"