

nor an environmental impact statement is required.

X. Request for Comments

This final rule includes reduced labeling requirements for products formulated and labeled as a lip protectant that meet the criteria established in § 201.66(d)(10) (*see* § 347.60(e)); for products containing only cocoa butter, petrolatum, or white petrolatum identified in § 347.10(d), (m), and (r), used singly or in combination with each other, and marketed other than as a lip protectant (*see* § 347.60(f)); for sunscreen drug products labeled for use only on specific small areas of the face (e.g., lips, nose, ears, and/or around eyes) and that meet the criteria established in § 201.66(d)(10) (*see* § 352.52(f)); and for combinations of skin protectant and sunscreen active ingredients (*see* § 352.60(b)(2), (c), and (d)). Some of this reduced labeling results from the modified labeling format for OTC drug products in § 201.66(d)(10), which did not exist when the TFM and amended TFM were published. Some of this reduced labeling is in response to comments specifically addressing petrolatum and white petrolatum, which the agency has extended to cocoa butter. The agency is providing 90 days for comment on the specific labeling requirements discussed in this section. Comments should be identified with the docket number found in brackets in the heading of this document. Three copies of all mailed comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Received comments may be seen in the Dockets Management Branch (*see ADDRESSES*) between 9 a.m. and 4 p.m., Monday through Friday. If the comments justify a change in labeling, the agency will propose to amend the final monographs accordingly at a later date. Because the amendment process can take a significant period of time, manufacturers of the products covered by this final rule should implement the labeling stated therein at this time, unless the compliance date has been stayed.

XI. References

The following references are on display in the Dockets Management Branch (*see ADDRESSES*) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. *The United States Pharmacopeia 24—National Formulary 19*, United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 2107–2118, 1999.

2. *Physicians' Desk Reference for Nonprescription Drugs and Dietary Supplements*, 20th ed., Medical Economics Co., Inc., Montvale, NJ, pp. 214–218, 1999.

3. "Emollients" and "Skin Protectants," in *Drug Facts and Comparisons*, Facts and Comparisons, Inc., St. Louis, MO, pp. 608–612, 1992.

4. Billow, J. A., "Dermatologic Products," in *Handbook of Nonprescription Drugs*, 10th ed., American Pharmaceutical Association, Washington, DC, pp. 521–541, 1993.

5. "Balsams and Resins" in *Martindale, The Extra Pharmacopeia* 28th ed., edited by J. E. F. Reynolds, The Pharmaceutical Press, London, England, p. 314, 1982.

6. *Remington's Pharmaceutical Sciences*, 15th ed., Mack Publishing Co., Easton, PA, p. 715, 1975.

7. Comment No. C00045, Docket No. 78N–0021, Dockets Management Branch.

8. *The United States Pharmacopeia 26—National Formulary 21*, United States Pharmacopeial Convention, Inc., Rockville, MD, p. 225, 2002.

9. Gosselin, R. E. et al., *Clinical Toxicology of Commercial Products*, 4th ed., Williams and Wilkins, Baltimore, MD, pp. 156–157, 1976.

10. Cullen, S. I., Al. Tonkin, and F. E. May, "Allergic Contact Dermatitis to Compound Tincture of Benzoin Spray," *The Journal of Trauma* 14:348–350, 1974.

11. Rademaker, M. and J. D. T. Kirby, "Contact Dermatitis to a Skin Adhesive," *Contact Dermatitis* 16:297–298, 1987.

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17. Lynfield, Y. L., L. P. Pertschuk, and A. Zimmerman, "Pemphigus Erythematosus Provoked by Allergic Contact Dermatitis," *Archives of Dermatology* 108:690–693, 1973.

18. Kokelj, F. and A. Contarutti, "Contact Dermatitis in Leg Ulcers," *Contact Dermatitis* 15:47–49, 1986.

19. Gough, D. C. S. and N. Lawton, "Circumcision—Which Dressing?," *British Journal of Urology* 65:418–419, 1990.

20. Letter from W. E. Gilbertson, FDA, to L. Gilson, Otis Clapp & Son, Inc., coded ANS002, Docket No. 78N–0301, Dockets Management Branch.

21. OTC Vol. 160034.

22. OTC Vol. 160165.

23. Comment No. C00062, Docket No. 78N–0021, Dockets Management Branch.

24. *Physicians' Desk Reference for Nonprescription Drugs*, 11th ed., Medical Economics Co., Inc., Oradell, NJ, p. 606, 1990.

25. Comments No. C0001 and SUP1, Docket No. 78N–021P, Dockets Management Branch.

26. Letters from J. S. Davis, FDA, to J. G. Valentino, U.S.P.C., dated April 10, 1990, and August 7, 1990, included in OTC Vol. 06DFM, Docket No. 78N–0021, Dockets Management Branch.

27. *Pharmacopeial Forum*, The United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 2798–2799, January through February 1992.

28. *Seventh Supplement to The United States Pharmacopeia 22—National Formulary 17*, The United States Pharmacopeial Convention, Inc., Rockville, MD, p. 3034, 1992.

29. Grais, M. L., "Role of Colloidal Oatmeal in Dermatologic Treatment of the Aged," *A.M.A. Archives of Dermatology and Syphilology* 68:402–407, 1953.

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31. Freeman, D. W., "Tape Dermatitis and Podiatry," in Comment SUP1, Docket No. 78N–021P, Dockets Management Branch.

32. Ignatoff, W. B., "The Use of Colloidal Oatmeal Therapy in Chirobody," in Comment SUP1, Docket No. 78N–021P, Dockets Management Branch.

33. Kürner, H., "Report on Therapeutic Experience With the Aveeno Series," *Zeitschrift für Hautkrankheiten* 50:631–635, 1975, Translation from German in Comment SUP1, Docket No. 78N–021P, Dockets Management Branch.

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44. Sulzberger, M. D. et al., "Principles of Topical Medication," in *Dermatology: Diagnosis and Treatment*, 2d ed., The Year Book Publishers, Inc., Chicago, IL, pp. 41–43, 1961, in Comment SUP1, Docket No. 78N–021P, Dockets Management Branch.

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