

comments, new data, and information to be submitted. Interested persons have already had an opportunity to submit comments, objections, or requests for an oral hearing on the TFM. Therefore, any comments at this time should only address the data and information submitted to the administrative record after April 9, 1984, and should specifically identify the data and information on which the comments are being provided. In addition, only new information related to the submissions being included in the administrative record at this time should be submitted. Any data and information previously submitted to this rulemaking need not be resubmitted. In establishing an FM, FDA will consider only comments, data, and information submitted prior to the closing of the administrative record following this current reopening.

Interested persons may submit to the Division of Dockets Management (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 paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## IX. Proposed Effective Date

FDA is proposing that any final rule that may issue based on this proposal become effective 12 months after its date of publication in the **Federal Register**.

## X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) under Docket No. 78N-0301 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. CP6.
2. OTC vol. 060051.
3. OTC vol. 060033.
4. OTC vol. 060052.
5. Comment No. LET39.
6. Comment No. C109.
7. Comment No. CP8.
8. Comment No. SUP8.
9. Comment No. LET46.
10. Comment No. RPT4.
11. Comment No. LET51.
12. Comment No. C111.
13. Comment No. LET57.
14. Comment No. LET66.
15. Comment No. PR1.
16. Comment No. PR2.

17. Comment No. CR9.
18. Comment No. CP13.
19. Comment No. C116.
20. Comment No. PR3.
21. Comment No. LET71.
22. Letter from M. Rapaport to D. Bowen, FDA, dated May 1, 1997.
23. Letter from M. Rapaport to L. Katz and S. Aurecchia, FDA, dated May 28, 1997.
24. Telefax from J. L. Boren, Argus Research, Inc., to M. Rapaport, dated June 17, 1997.
25. Letter from M. Rapaport to S. Aurecchia, FDA, dated June 23, 1997.
26. Letter from M. Rapaport to L. Katz and S. Aurecchia, FDA, dated July 1, 1997.
27. Comment No. LET84.
28. Letter from M. Rapaport to E. Yuan, FDA, dated April 1, 2000.
29. Comment No. SUP9.
30. Comment No. SUP10.
31. Comment No. SUP11.
32. Comment No. LET49.
33. Comment No. LET50.
34. Comment No. LET55.
35. Comment No. LET61.
36. Comment No. MM9.
37. Comment No. LET67.
38. Comment No. LET68.
39. Comment No. LET69.
40. Comment No. LET70.
41. Comment No. PDN2.
42. Comment No. LET85.
43. Comment No. MM10.
44. Comment No. LET86.

## List of Subjects in 21 CFR Part 348

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 348 (as proposed in the **Federal Register** of February 8, 1983 (48 FR 5852)) be amended as follows:

## PART 348—EXTERNAL ANALGESIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 348 continues to read as follows:

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

2. Section 348.10 is amended by revising the introductory text to read as follows:

### § 348.10 Analgesic, anesthetic, and antipruritic active ingredients.

The active ingredients of the product consist of any of the following, within the established concentration for each ingredient, but not for use in a patch, plaster, or poultice dosage form:

\* \* \* \* \*

3. Section 348.12 is amended by revising the introductory text to read as follows:

### § 348.12 Counterirritant active ingredients.

The active ingredients of the product consist of any of the following, within the established concentration for each ingredient, but not for use in a patch, plaster, or poultice dosage form:

\* \* \* \* \*

Dated: July 7, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-17934 Filed 7-16-03; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### 24 CFR Part 3282

[Docket No. FR-4867-N-01]

### Manufactured Housing Consensus Committee—Rejection of Land Use Proposal

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

**ACTION:** Notice of Rejection of Manufactured Housing Consensus Committee Recommendation of Proposed Regulation.

**SUMMARY:** The Secretary has rejected a proposed recommendation by the Manufactured Housing Consensus Committee to promulgate a regulation concerning restrictions on the use of land for the placement of manufactured housing. The Secretary has determined that the Department has no legal authority to promulgate such a regulation under the National Manufactured Housing Construction and Safety Standards Act of 1974.

### FOR FURTHER INFORMATION CONTACT:

William W. Matchneer III, Administrator, Manufactured Housing Program, U.S. Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410-8000; telephone (202) 708-6401 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Information Relay Service at (800) 877-8339.

**SUPPLEMENTARY INFORMATION:** The Manufactured Housing Consensus Committee has transmitted to the Secretary a recommendation dated March 14, 2003, that the Manufactured Housing Home Procedural and Enforcement Regulations, 24 CFR part 3282, be amended to include the following statement:

“No state or local jurisdiction shall allow a landowner to place restrictions