

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

on their [sic] land prohibiting homes built to the federal manufactured home construction and safety standards when the landowner allows other forms of single-family residential construction.”

I. Background: Applicable Statutory Provisions.

Consensus Committee. The Consensus Committee was established by the National Manufactured Housing Construction and Safety Standards Act of 1974, 42 U.S.C. 5401 *et seq.* (“the Act”) for the purpose of providing periodic recommendations to the Secretary to adopt, revise, and interpret the federal manufactured housing construction and safety standards and the procedural and enforcement regulations. 42 U.S.C. 5403(a)(3)(A). It may submit to the Secretary proposed procedural and enforcement regulations and recommendations for the revision of the regulations. 42 U.S.C. 5403(b)(1).

Within 120 days from the date on which the Secretary receives a proposed procedural or enforcement regulation from the Consensus Committee, the Secretary must approve or reject the proposal. If he rejects the proposal, he must provide to the Consensus Committee a written explanation of the reasons for rejection and publish in the **Federal Register** the rejected proposal and the reasons for the rejection. 42 U.S.C. 5403(b)(4).

Preemption. It appears that the legal underpinning of the Consensus Committee’s recommendation is the preemption provision of the Act, 42 U.S.C. 5403(d). The preemption provision allows federal construction and safety standards promulgated under the Act to preempt state and local laws. See “Notice of Staff Guidance, 62 FR 3456 (1997);” “Statement of Policy,” 62 FR 24337 (1997). The provision states that Federal construction and safety standards promulgated under the Act preempt state and local laws to the extent that such are applicable to the same aspect of performance of a manufactured home and are not identical to Federal construction and safety standards. 42 U.S.C. 5403(d).

Congress amended the preemption provision in 2000 to provide that preemption “shall be broadly and liberally construed to ensure that disparate state or local requirements or standards do not affect the uniformity and comprehensiveness of the [Federal construction and safety] standards promulgated under this section nor the Federal superintendence of the manufactured housing industry as established by this title [the Act].” 42 U.S.C. 5403(d).

This amendment to the Act provided explicit statutory support for paragraph (d) of HUD’s regulation at 24 CFR 3282.11 that implements the preemption authority. Paragraph (d) states: “No State or locality may establish or enforce any rule or regulation or take any action that stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. The test of whether a State rule or action is valid or must give way is whether the State rule can be enforced or the action taken without impairing the Federal superintendence of the manufactured home industry as established by the Act.”

The U.S. Court of Appeals for the 11th Circuit had raised a concern as to whether this paragraph was valid, stating that section 3282.11(d) “seems to expand the scope of the unambiguous preemption provision enacted by Congress.” *Georgia Manufactured Housing v. Spalding County*, 148 F.3d 1304, n8 (11th Cir. 1998).

The amendment expressed Congress’ intent that the preemption over local construction standards should be construed so as to recognize the nationwide scope of the Federal manufactured housing program and the manufactured housing industry.

The amendment did not modify the basic substance of the statutory preemption provision. By its specific terms, the provision apply to construction and safety standards, generally codified in 24 CFR part 3280. It does not apply to other regulations, including the Manufactured Home Procedural and Enforcement Regulations in 24 CFR part 3282.

The 2000 Congressional amendments also revised the Purpose of the Act to include, “to facilitate the availability of affordable manufactured homes and to increase homeownership for all Americans”, 42 U.S.C. 5401(b)(2). The amendment cannot be found to expand the applicability of the preemption provision beyond the federal construction and safety standards. There is no indication of congressional intent to preempt local land use or zoning laws. *Accord, Burton v. City of Alexander City*, 2001 U.S. Dist. LEXIS 6651, M.D. Ala. 2001. (“* * * Congress plainly did not intend to preempt zoning laws that operate only where HUD does not. The most that can be said about the 2000 Act is that it removed any possible ambiguity created by a cryptic footnote in *Spalding County* * * * See 148 F.3d 1309 n.8.”).

Authority of the Secretary and the Administrative Procedure Act. All regulations promulgated by the

Department must be consistent with a statutory grant of authority. Generally, with respect to the manufactured housing program that authority would be found in a specific authority such as in the Act or in some general authority such as that found in Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d). All regulations must also comply with the procedural and substantive requirements of the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.* Under the APA, federal regulations will be held unlawful and set aside if found to be “in excess of statutory jurisdiction, authority, or limitations, or shore of statutory right * * *” 5 U.S.C. 706(2).

Decision of the Secretary

The Secretary rejects the proposed recommendation of the Consensus Committee. The Secretary need not publish the proposal or his reasons for rejection for the following reasons. Nevertheless, since the proposal is the first recommendation issued by the Consensus Committee, the Secretary is publishing the proposal and his reasons for rejection in order to explain the statutory limitations on the Consensus Committee’s authority and the Secretary’s obligations under the Act.

Bases for Rejection. 1. The Act gives no specific jurisdiction or authority to the Consensus Committee to proposed procedural or enforcement regulations that have no relationship to the revision or enforcement of the federal construction and safety standards. As such, the proposed regulation is beyond the authority granted by the Act to the Consensus Committee to propose and is beyond the scope of what the Secretary is required to respond to under the procedures established in the Act.

The jurisdiction of the Consensus Committee is limited by the provisions of the Act. The Consensus Committee may make recommendations to adopt, revise, or interpret the procedural and enforcement regulations. The Consensus Committee does not have authority under the Act to make recommendations concerning the Procedural and Enforcement Regulations that are beyond the scope of the regulations.

The scope of 24 CFR 3282.1(b), the Procedural and Enforcement Regulations, is to prescribe procedures for the implementation of the Secretary’s responsibilities under the Act to conduct inspections and investigations necessary to enforce the federal construction and safety standards, to determine that a manufactured home fails to comply

with an applicable standard or contains an imminent safety hazard, and to direct manufacturers to notify owners, and to remedy violations of the federal construction and safety standards and, in some cases, to remedy the defect or imminent safety hazard.

The proposal is a mandate upon local jurisdiction to prohibit landowners from restricting the use of their land. The use of real property, or private or contractual restrictions upon it, is not within the scope of the Secretary's authority under the Act or within the applicability of the procedural and enforcement regulations.

2. Regardless of the authority given to the Consensus Committee under the Act to propose regulations, it proposal would seek the expand the authority of the Department beyond a reasonable interpretation of any provisions in the Act.

The Department may not expand its jurisdiction of the limitations of its statutory powers through statutory interpretation. The Department's statutory jurisdiction and authority must be delegated to it by Congress and be found within an authorizing provision of a statute. 5 U.S.C. 706(2).

The proposal is not based upon the federal construction and safety standards or the enforcement of those federal standards. It seeks to establish mandates on state and local jurisdictions, and to expand responsibilities and authority beyond what Congress had granted by requiring HUD to become involved in state and local land use issues and to take remedial action against local governments if they do not comply. There is no congressional authorization in the Act permitting or mandating the Department to be involved in such issues. As such, any actions by the Secretary to promulgate the proposal would be held unlawful under the APA.

HUD has long interpreted its authority under the Act to exclude involvement in local land use issues. 62 FR 3456, 3458 (1997). It had not previously interpreted the preemption provisions in the Act to preempt local laws unless the local laws involved building or construction standards. There is nothing in the Act or in the legislative history of the Act that would suggest a directive by Congress to change HUD's long-held legal position.

In addition, there is no applicable authority under any other statutory grant of power of the Secretary. The action requested by the Consensus Committee is not within any general authority of the Secretary, such as it granted in Section 7(d) of the

Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

For HUD to promulgate and enforce a regulation of such massive impact upon individual landowners and local jurisdictions nationwide and to assert federal involvement in areas traditionally reserved to the states, the Department would need a more specific statement from Congress of its intent.

3. The proposed regulation does not delineate a procedure by which state or local jurisdictions are to ascertain or to prohibit restrictions on land use nor a procedure by which the Department is to enforce against a state or local jurisdiction that does not comply. While the proposal purports to create a mandate, the regulation is only one sentence and does not contain any structure by which to enforce it or to ascertain violations. As such, the regulation is administratively incomplete.

Accordingly, for these reasons, the Secretary rejects the proposed regulation of the Consensus Committee.

Dated: July 11, 2003.

John C. Weicher,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. 03-18175 Filed 7-15-03; 10:08 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[REG-144908-02]

RIN 1545-BB66

Federal Unemployment Tax Deposits— De Minimis Threshold

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the deposit of Federal Unemployment Tax Act (FUTA) taxes. The proposed regulations would provide an additional exception to the FUTA deposit requirements for taxpayers that qualify for the *de minimis* exception to the deposit requirements applicable to Federal Insurance Contribution Act (FICA) and withheld income taxes. The regulations affect small employers required to make deposits of FUTA taxes.

DATES: Written or electronically generated comments and requests for a public hearing must be received by October 15, 2003.

ADDRESSES: Send submissions to: CC:PA:RU (REG-144908-02), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:RU (REG-144908-02), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet directly to the IRS Internet site at <http://www.irs.gov/regs>.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Heather L. Dostaler, (202) 622-4940; concerning submissions of comments and requests for a public hearing, Treena Garrett of the Regulations Unit at (202) 622-7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

The current rules relating to the deposit of FUTA taxes require employers to deposit taxes on a quarterly basis. The only generally applicable exception to this requirement is for employers whose accumulated FUTA taxes (*i.e.*, FUTA taxes for the current quarter plus undeposited FUTA taxes for prior quarters) do not exceed \$100. These employers are not subject to the deposit requirements until the quarter in which accumulated FUTA taxes exceed \$100. Similarly, if FUTA tax liability for a calendar year exceeds deposits for the year, the employer may remit the balance with the annual return only if it does not exceed \$100. In all other cases, the balance must be deposited with an authorized financial institution.

An employer is also generally required to deposit FICA taxes and withheld income taxes (employment taxes) on at least a monthly basis and file a quarterly or annual employment tax return. For any return period in which the employer's total liability for these taxes is less than \$2,500, the employer may satisfy its deposit obligation by remitting the tax with a timely filed employment tax return. An employer that qualifies for this exception with respect to employment taxes accumulated during a return period may, nevertheless, be required to deposit FUTA taxes for that period if the amount of accumulated FUTA taxes exceeds \$100.

Explanation of Provisions

The proposed regulations would provide an additional exception to the FUTA deposit requirements for