consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the Federal Register of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC antitussive drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC antitussive drug products is not expected to pose such an impact on small businesses. This final rule imposes one-time costs associated with changing product labeling to include the MAOI-dextromethorphan drug interaction precaution statement. In the proposed rule (57 FR 27666 at 27669), the agency encouraged manufacturers of OTC antitussive drug products to voluntarily implement this labeling as of the date of publication of the proposal, subject to the possibility that FDA may change the wording of the drug interaction precaution as a result of comments filed in response to the proposal. Because the agency encouraged voluntary implementation of the proposed drug interaction precaution statement, manufacturers were advised that they would be given ample time after publication of the final rule to use up any labeling implemented in conformance with the proposal. Any manufacturer that voluntarily implemented labeling in conformance with the proposal and that now needs more than 12 months to use up that labeling should contact the Division of Drug Labeling Compliance (HFD–310), Office of Compliance, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) 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.

List of Subjects in 21 CFR Part 341

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 341 is amended as follows:

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 341.74 is amended by adding new paragraphs (c)(4)(v) and (c)(4)(vi) to read as follows:

§ 341.74 Labeling of antitussive drug products.

* * * * *

(c) * * *

(4) * * *

(v) *For products containing dextromethorphan or dextromethorphan hydrobromide as identified in § 341.14(a)(3) and (a)(4) when labeled for adults or for adults and children under 12 years of age. "Drug interaction precaution.* Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product."

(vi) *For products containing dextromethorphan or dextromethorphan hydrobromide as identified in § 341.14(a)(3) and (a)(4) when labeled only for children under 12 years of age. "Drug interaction precaution.* Do not give this product to a child who is taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your child's prescription drug contains an MAOI, consult a health professional before giving this product."

* * * * *

Dated: August 17, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–25674 Filed 10–19–93; 8:45 am]

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federal register

Wednesday
October 20, 1993

Part VII

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 341

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph for OTC Bronchodilator Drug Products

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

[Docket No. 91N–0323]

RIN 0905–AA06

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph for OTC Bronchodilator Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule amending the final monograph for over-the-counter (OTC) bronchodilator drug products to modify the drug interaction precaution statement required in the labeling of OTC bronchodilator drug products containing sympathomimetic amine drugs. These drug products should not be used by persons who are taking a prescription drug containing a monoamine oxidase inhibitor (MAOI), without first consulting a health professional. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: October 20, 1994.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION

I. Background

In the Federal Register of September 9, 1976 (41 FR 38312), FDA published an advance notice of proposed rulemaking for OTC cold, cough, allergy, bronchodilator, and antiasthmatic drug products. The Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel) recommended the following warning statement for the labeling of OTC bronchodilator drug products: "*Drug Interaction Precaution.* Do not take this product if you are presently taking a prescription antihypertensive or antidepressant drug containing a monoamine oxidase inhibitor." The warning was based on data showing marked and potentially dangerous increases in blood pressure in patients taking MAOI drugs and sympathomimetic amine bronchodilator drugs (41 FR 38312 at 38370 through 38373).

The agency discussed this statement in the tentative final monograph for OTC bronchodilator drug products (47 FR 47520 at 47523, October 26, 1982). In response to the Panel's recommendation, one comment contended that terms such as "antihypertensive," "antidepressant," and "monoamine oxidase inhibitor" are highly technical; that only a small percentage of the population is likely to understand this warning; and that including such a warning in the labeling of an OTC drug is contrary to the well-established principle that unnecessary or confusing precautions tend to dilute the significance of all instructions in the labeling and, hence, should be avoided (47 FR 47520 at 47523).

The agency acknowledged that the Panel's proposed drug interaction precaution might not be readily understood by all consumers. However, the agency considered a statement of this type to be necessary to alert consumers because antihypertensive and antidepressant drugs are widely prescribed. The agency proposed to simplify the precaution by substituting the term "high blood pressure" for "antihypertensive," and the term "depression" for "antidepressant." The agency also believed that the words "monoamine oxidase inhibitor" would be confusing to consumers and were not needed in the precautionary statement to convey the intended message. Accordingly, the agency proposed the following: "*Drug interaction precaution.* Do not take this product if you are presently taking a prescription drug for high blood pressure or depression, without first consulting your doctor." (See proposed § 341.76(c)(3) at 47 FR 47527.) In the final monograph for OTC bronchodilator drug products, published in the Federal Register of October 2, 1986 (51 FR 35326 at 35338), the agency substituted the word "use" for the word "take," because "use" can apply to both inhalation and oral dosage forms. This statement appears in § 341.76(c)(4) of the final monograph.

In the Federal Register of June 19, 1992 (57 FR 27662), FDA published a notice of proposed rulemaking to amend the final monograph for OTC bronchodilator drug products to revise the drug interaction precaution to read: "*Drug interaction precaution.* Do not use this product if you are taking a prescription drug containing a monoamine oxidase inhibitor (MAOI) (certain drugs for depression or psychiatric or emotional conditions), without first consulting your doctor. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product." The agency invited written comments by August 18, 1992, on the specific wording of the warning, and the best way to convey this information to persons who are taking MAOI drugs.

In the Federal Register of August 6, 1992 (57 FR 34733), the agency extended the comment period to October 5, 1992, to obtain additional comments on whether the drug interaction precaution statement should be expanded to include MAO B drugs, such as selegiline. The agency asked whether the proposed drug interaction statement should be expanded to read: "*Drug interaction precaution.* Do not use this product if you are taking a prescription drug containing a monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), without first consulting your doctor. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product." The agency invited comments and information on interactions between selegiline and sympathomimetic amines and asked whether, from a public health perspective, it would be appropriate to expand the bronchodilator drug interaction precaution, as indicated.

Elsewhere in this issue of the Federal Register, the agency is amending the final monograph for OTC antitussive drug products so that the MAOI drug interaction precautions are consistent for OTC bronchodilator and antitussive products. In a future issue of the Federal Register, the agency intends to include the same drug interaction precautions in the final rule for OTC nasal decongestant drug products. These statements will apply to oral nasal decongestants containing sympathomimetic amine drugs.

In response to the proposed rule, the agency received comments from one physician, one drug manufacturer, and one drug manufacturers' association. Copies of the comments are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. The primary focus of the comments is alternative wording for the new drug interaction precaution statement.

II. The Agency's Conclusions on the Comments

1. One comment stated that the agency's proposal was thorough, contained an excellent review of the existing medical knowledge, and shows

that there is a significant body of information to support the drug interaction precaution. The comment suggested that the drug interaction precautions for OTC antitussive, bronchodilator, and nasal decongestant drug products be consistent because the three groups are quite similar.

The agency agrees that the warning for OTC antitussive, bronchodilator, and oral nasal decongestant drug products should be consistent. Precautions for antitussive and bronchodilator drug products are addressed in this issue of the **Federal Register**. The same drug interaction precautions will be included in the final monograph for OTC nasal decongestant drug products in a future issue of the **Federal Register**.

2. One comment was submitted only to the proposed rule for OTC antitussive drug products (Docket No. 90N–0420), but is being discussed here because it pertains to the wording of the drug interaction precaution statement. Based on experience with labeling used on its own dextromethorphan-containing products, the comment suggested the following wording: "*Drug Interaction Precaution:* Do not take this product if you are presently taking a prescription monoamine oxidase inhibitor without first consulting your physician." For products labeled only for children under 12 years of age, the comment suggested: "*Drug Interaction Precaution:* Do not give this product to a child who is presently taking a prescription monoamine oxidase inhibitor without first consulting your child's physician." The comment stated that professional labeling for its dextromethorphan-containing drug products has included an MAOI interaction statement since 1977. The comment added that consumer labeling for its OTC drug product containing dextromethorphan and guaifenesin once used the statement: "*Drug Interaction Precaution:* Do not take this product if you are presently taking a prescription drug for high blood pressure or depression without first consulting your doctor." The same statement was proposed in the tentative final monograph for OTC bronchodilator drug products (47 FR 47520 at 47527) and the tentative final monograph for OTC nasal decongestant drug products (50 FR 2220 at 2239, January 15, 1985). The comment complained that this language appeared to cause confusion among health professionals and consumers, so it was subsequently modified to read: "*Drug Interaction Precaution:* Do not take this product if you are presently taking a prescription monoamine oxidase inhibitor without first consulting your physician." The comment stated that this newer language has provided a clear, succinct message to consumers, physicians, and other health professionals. The comment added that when MAOI drugs are prescribed, patients are fully informed about all necessary precautions and are provided with informational brochures on the many foods and drugs with known MAOI interactions.

The agency disagrees that the comment's suggested wording adequately conveys all information necessary for consumers to make an appropriate decision regarding use of the OTC drug product. Specifically, the suggested wording does not include an abbreviated name for monoamine oxidase inhibitor, the likely medical uses for the MAOI, or provide for consultation with health professionals other than doctors. The agency acknowledges that this additional information lengthens the precaution. However, the serious nature of the adverse reactions requires that people taking MAOI drugs should be given as much information as possible, so that they can make the correct decision about the use of the OTC drug product. The term "monoamine oxidase inhibitor" alone is technical and may not be as easily remembered as the shorter term "MAOI." Accordingly, the agency believes that both terms should be used. Some consumers may remember one term, while other consumers may remember the other term. Having both terms in the precaution helps ensure greater recognition among more consumers. Also, those consumers who do not recognize either term may at least recognize that their prescription drug is for one of the indications listed. Hopefully, such persons will consult their doctor or other health professional before taking the OTC drug product. The agency acknowledges that when MAOI drugs are prescribed, patients should be fully informed of the precautions and interactions associated with the drug. However, the agency is concerned that some patients may not be fully informed about the MAOI drug, may not fully understand or remember all the information given them or, with the passage of time, may forget or lose information that has been provided. The agency believes the OTC drug product labeling should be as informative as possible and should reinforce the MAOI prescribing information. Accordingly, the comment's suggested language is not adopted.

3. One comment suggested deleting the statement "If you are uncertain whether your prescription drug contains an MAOI, consult a health professional." The comment stated that a general informational statement urging consumers to use common sense should not be a part of the drug interaction precaution. The comment argued that the statement adds lengthy wording to already crowded labeling, is inappropriately placed as part of a specific warning, is redundant in the contexts of available patient education and of the common sense consumers apply to self-medication practice, and is not supported by adequate documentation or recommendations of the Panel.

The agency disagrees with the comment. The agency included this statement out of concern for consumers who may not understand the technical terms used in the precaution, may not remember whether their prescription drug is an MAOI, or may not retain the informational brochures received when the MAOI drug was prescribed. The agency is also concerned that some consumers who wish to use an OTC drug product may not want to bother their doctor with questions about their medication. Because of the possible severity of the adverse reactions, the agency believes it is important to tell consumers that if there is any uncertainty or doubt about using the OTC drug product, a health professional should be consulted. It is also important to remind consumers who may be reluctant to ask their doctor that other health professionals, such as pharmacists or nurses, can be alternative sources of information. The agency does not believe that label space should limit essential safety information. There are means available to extend label space, such as carton flaps or package inserts. Finally, the wording in this statement is similar to other labeling that the Panel proposed for oral nasal decongestant drug products ("except under the advice and supervision of a physician," 41 FR 38312 at 38423), and to language in the final monograph for OTC bronchodilator drug products ("without first consulting your doctor," § 341.76(c)(4)).

4. One comment urged the agency to include only those aspects of prescription labeling that are formally approved indications. The comment stated that the approved indication for MAOI drugs is depression, and the precaution statement should explicitly reference "depression" and not include overly broad references to unapproved uses, e.g., "emotional disturbances." The comment stated that it is commonplace for prescription drugs, approved for one or more conditions, to be used experimentally in private practice or in formal clinical trials to

treat conditions that do not appear in the approved prescription labeling. The comment asserted, however, that the establishment of OTC drug labeling that would accommodate ever-changing unapproved uses of the prescription drug would abuse the OTC drug product labeling. The comment suggested other approaches, such as notification of physicians and pharmacists by direct mail or through medical publications, press releases, prescription labeling, and professional organizations.

The parenthetical information, "certain drugs for depression or psychiatric or emotional conditions," was intended to alert consumers who may be taking a MAOI drug for a condition other than depression or a condition not readily identified with the term depression, such as anxiety or phobia. The agency noted in the proposal (57 FR 27662) that these uses are described in the scientific literature. In addition, the prescribing information for one MAOI, phenelzine sulfate, states the following: "[Phenelzine sulfate] has been found to be effective in depressed patients clinically characterized as 'atypical,' 'nonendogenous,' or 'neurotic.' These patients often have mixed anxiety and depression and phobic or hypochondriacal features." (Ref. 1). Because people are currently being prescribed MAOI drugs for conditions other than depression, the agency believes that these uses cannot be ignored. Consumers who take the drug for one of these other conditions need to be informed. Further, the language adopted will accommodate a certain amount of increased use of MAOI drugs, as described in the scientific literature, without the need to revise the OTC drug product labeling to cover such uses. The agency does not consider the other approaches suggested by the comment to be adequate because they target the health care professional rather than the consumer. While all of those approaches can and should be used, the consumer must be informed. Therefore, the agency is not adopting the comment's suggestions.

Reference

(1) Approved labeling for phenelzine sulfate (Parke-Davis), in OTC Vol. 04BFMA2, Docket No. 91N–0323, Dockets Management Branch.

5. One comment suggested that the precaution statement include a 2-week washout period to help ensure that patients will not discontinue the use of the MAOI in order to use the OTC drug. The comment proposed the following wording: "Do not use this product if you are presently taking a prescription monoamine oxidase inhibitor (MAOI) for depression or for 2 weeks after stopping use of a MAOI without first consulting your doctor." The comment stated that the suggested 2-week washout period was based on scientific data, and provided references and studies in support.

One reference provided by the comment stated that the MAOI drugs used clinically in the United States are irreversible enzyme inhibitors, that return of monoamine oxidase activity following administration of an irreversible MAOI is presumably dependent upon enzyme synthesis, and that recovery of monoamine oxidase activity after irreversible inhibition may require up to 2 weeks following withdrawal of the MAOI drug (Ref. 1). Two studies submitted by the comment suggest that the rate of recovery of monoamine oxidase activity may be organ-specific and also possibly influenced by body weight and age (Refs. 2 and 3). In a study with normal volunteers, the apparent half-lives of plasma MAO and platelet MAO were determined to be 2 to 3 days and 9 days, respectively (Ref. 4). In a study of the interaction between sympathomimetic amines (phenylephrine, ephedrine, and noradrenaline) and MAOI's in normal volunteers, results showed a rise in blood pressure from phenylephrine and ephedrine during MAOI administration and for up to 14 days after discontinuation of the MAOI (Ref. 5).

The agency has reviewed the studies and information submitted by the comment and agrees that it is important to include a 2-week washout period in the precaution statement. The prescribing information for MAOI drugs states that 10 to 14 days should elapse between discontinuation of an MAOI and initiation of treatment with certain other drugs, e.g., another antidepressant, another MAOI, or general anesthesia (Refs. 6, 7, and 8). The prescribing information for tranylcypromine sulfate, a partially reversible MAOI, states that monoamine oxidase activity is recovered in 3 to 5 days, and also recommends a 10-day withdrawal period between treatments (Ref. 8).

The agency concludes that information about a withdrawal period is important, for several reasons: (1) It should discourage patients from stopping their MAOI medication to take an OTC cough-cold drug product, and (2) it will help ensure that if the MAOI medication is discontinued for any reason, the OTC drug product will not be used before all or most of the MAOI is no longer in the body. Therefore, the agency is adopting the comment's suggestion to include a 2-week washout period, but is modifying the wording slightly. The comment proposed, "* * * if you are presently taking * * *," which the agency is shortening to "* * * if you are now taking * * *."

References

(1) Baldessarini, R.J., "Drugs and the Treatment of Psychiatric Disorders," in "Goodman and Gilman's The Pharmacological Basis of Therapeutics," 8th ed., edited by A.G. Gilman et al., Macmillan Publishing Co., New York, pp. 414–419, 1990.

(2) Della Corte, L., and B.A. Callingham, "The Influence of Age and Adrenalectomy on Rat Heart Monoamine Oxidase," *Biochemical Pharmacology*, 26:407–415, 1977.

(3) Planz, G., K. Quiring, and D. Palm, "Rates of Recovery of Irreversibly Inhibited Monoamine Oxidases: A Measure of Enzyme Protein Turnover," *Naunyn-Schmiedeberg's Archives of Pharmacology*, 273:27–42, 1972.

(4) Palm, D. et al., "Quantitation of Irreversible Inhibition of Monoamine Oxidase in Man," *European Journal of Clinical Pharmacology*, 3:82–92, 1971.

(5) Elis, J. et al., "Modification by Monoamine Oxidase Inhibitors of the Effect of Some Sympathomimetics on Blood Pressure," *British Medical Journal*, 2:75–78, 1967.

(6) Approved labeling for phenelzine sulfate (Parke-Davis), in OTC Vol. 04BFMA2, Docket No. 91N–0323, Dockets Management Branch.

(7) Approved labeling for isocarboxazid (Roche), in OTC Vol. 04BFMA2, Docket No. 91N–0323, Dockets Management Branch.

(8) Approved labeling for tranylcypromine sulfate (SmithKline Beecham), in OTC Vol. 04BFMA2, Docket No. 91N–0323, Dockets Management Branch.

6. Two comments discussed possible interactions between MAO B inhibitors, such as selegiline, and OTC drug products containing dextromethorphan or sympathomimetic amines. One comment stated that it had reviewed all spontaneous reports of adverse drug experiences with its MAO B inhibitor drug product containing selegiline, as monitored in accordance with 21 CFR 314.80. The comment found no mention of a suspected drug interaction with, or concomitant use of, an OTC drug product containing dextromethorphan or sympathomimetic amines. The other comment urged the agency to limit drug interaction precautions to those that have been shown to be of significant, practical, and likely importance. Specifically, the comment stated that in the case of the selective MAOI selegiline, the approved indication is Parkinson's disease, but that disease should not be included in the OTC drug product precaution statement because the prescription package insert for selegiline explicitly states that drug-drug interactions are not likely to occur between selegiline and OTC drugs.

The agency disagrees with the comment's interpretation of the package insert for selegiline. The insert (Ref. 1) states the following:

In theory, therefore, because MAO A of the gut is not inhibited, patients treated with selegiline at a dose of 10 milligrams (mg) a day can take medications containing pharmacologically active amines and consume tyramine-containing foods without risk of uncontrolled hypertension. To date, clinical experience appears to confirm this prediction; cheese reactions have not been reported in selegiline treated patients. The pathophysiology of the "cheese reaction" is complicated and, in addition to its ability to inhibit MAO B selectively, selegiline's apparent freedom from this reaction has been attributed to an ability to prevent tyramine and other indirect acting sympathomimetics from displacing norepinephrine from adrenergic neurons. However, until the pathophysiology of the cheese reaction is more completely understood, it seems prudent to assume that selegiline can only be used safely without dietary restrictions at doses where it presumably selectively inhibits MAO B (e.g., 10 mg/day). In short, attention to the dose dependent nature of selegiline's selectivity is critical if it is to be used without elaborate restrictions being placed on diet and concomitant drug use.

The insert for selegiline further states:

Since the selective inhibition of MAO B by selegiline hydrochloride is achieved only at doses in the range recommended for the treatment of Parkinson's disease (e.g., 10 mg/day), overdoses are likely to cause significant inhibition of both MAO A and MAO B. Consequently, the signs and symptoms of overdose may resemble those observed with marketed nonselective MAO inhibitors (e.g., tranylcypromine, isocarboxazid, and phenelzine).

The agency is aware that Blackwell has reported that, while selegiline at low dosage inhibits only MAO B, at antidepressant dosages (over 20 mg daily) the drug loses its specificity and hypertensive reactions begin to occur (Ref. 2).

The insert also describes interactions between selegiline and meperidine, which is typical of the interaction of meperidine with other MAOI drugs. The drug interaction section of the insert states: "No interactions attributed to the combined use of selegiline and other drugs have been reported. However, because the data base of documented clinical experience is limited, the level of reassurance provided by this lack of adverse reporting is uncertain."

The loss of selectivity at doses higher than 10 mg per day raises concerns that drug interactions may occur. Further, the agency does not find the lack of adverse reaction reports for selegiline to be reassuring. Selegiline is a recently approved new drug with limited marketing experience. In view of the potentially fatal outcome of an interaction between MAOI drugs and sympathomimetic amines and the limited data base for selegiline, the agency believes that the potential for interaction should be assumed and that prudence is the wisest course until more information is available. Therefore, the agency is including the words "Parkinson's disease" in the precaution statement.

References

(1) Approved labeling for selegiline hydrochloride (Somerset), in OTC Vol. 04BFMA2, Docket No. 91N–0323, Dockets Management Branch.

(2) Blackwell, B., "Monoamine Oxidase Inhibitor Interactions with Other Drugs," Journal of Clinical Psychopharmacology, 11:55–59, 1991.

III. The Agency's Final Conclusions on the Drug Interaction Precaution Statement

The agency concludes that a revised drug interaction precaution statement for OTC bronchodilator drug products is needed to better inform consumers of the potential interaction with various MAOI drugs. To be fully informative to consumers, this statement should contain both the technical and abbreviated terms for monoamine oxidase inhibitor (MAOI), should include likely medical uses for the MAOI drugs, should mention a 2-week washout period, and should include the statement to consult a health professional if uncertainty about the MAOI drug exists. Accordingly, the agency is amending § 341.76(c)(4) to read: "*Drug Interaction Precaution.* Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product."

IV. Economic Impact

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking. The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC bronchodilator drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC bronchodilator drug products is not expected to pose such an impact on small businesses. This final rule imposes one-time costs associated with changing product labels to include the MAOI-bronchodilator interaction precaution statement. In the proposed rule (57 FR 27662 at 27663), the agency encouraged manufacturers of OTC bronchodilator drug products to voluntarily implement this labeling as of the date of publication of the proposal, subject to the possibility that FDA may change the wording of the drug interaction precaution as a result of comments filed in response to the proposal. Because the agency encouraged voluntary implementation of the revised drug interaction precaution statement, manufacturers were advised that they would be given ample time after publication of the final rule to use up any labeling implemented in conformance with the proposal. Any manufacturer that voluntarily implemented labeling in conformance with the proposal and that now needs more than 12 months to use up that labeling should contact the Division of Drug Labeling Compliance (HFD–310), Office of Compliance, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) 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.

List of Subjects in 21 CFR Part 341

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 341 is amended as follows:

PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 341.76 is amended by revising paragraph (c)(4) to read as follows:

§ 341.76 Labeling of bronchodilator drug products.

* * * * *

(c) * * *

(4) "*Drug interaction precaution.* Do not use this product if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product."

* * * * *

Dated: August 17, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–25675 Filed 10–19–93; 8:45 am]

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federal register

Wednesday
October 20, 1993

Part VIII

Department of Housing and Urban Development

Office of the Secretary

24 CFR Parts 203 and 291
Single Family Property Disposition Program; Interim Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Parts 203 and 291

[Docket No. R–93–1670; FR–3253–I–01]

RIN 2502–AF75

Single Family Property Disposition Program

AGENCY: Office of the Secretary, HUD.

ACTION: Interim rule.

SUMMARY: This rule amends the regulations at 24 CFR part 291 governing the Single Family Property Disposition program to change the existing policy on the maximum closing costs HUD will pay, discounts off list price in direct sales to governmental entities and non-profit organizations, extensions to the contract closing time, return of earnest money deposits, and priority to owner-occupant purchasers. The rule announces the availability of purchase money mortgages for nonprofit organizations and governmental entities purchasing properties for use in programs that promote affordable homeownership. The rule also includes changes to the occupied conveyance regulations in 24 CFR part 203 to allow conveyance of occupied property where the high cost of eviction or relocation expenses makes eviction impractical.

DATES: Effective date: November 19, 1993.

Comment due date: December 20, 1993.

ADDRESSES: Interested persons are invited to submit comments regarding this rule to the Office of the General Counsel, Rules Docket Clerk, room 10276, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410–0500. Communications should refer to the above docket number and title. Facsimile (FAX) comments are not acceptable. A copy of each communication submitted will be available for public inspection and copying during regular business hours (7:30 a.m. to 5:30 p.m. Eastern Time) at the above address.

FOR FURTHER INFORMATION CONTACT: Robert Falkenstein, Jr., Acting Director, Single Family Property Disposition, room 9172, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410–0500; telephone (202) 708–0740; TDD for hearing- and speech-impaired (202) 708–4594. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: The changes in this rule do not affect the information collection requirements for the Single Family Property Disposition program, which were previously approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act and assigned OMB control numbers 2502–0306.

I. Background

Title II of the National Housing Act (the Act) authorizes HUD to insure mortgages for single family residences through the Federal Housing Administration (FHA) single family mortgage insurance program. The disposition program for single family properties, acquired by HUD in exchange for payment of insurance claims, is authorized by section 204(g) of the Act. On September 16, 1991 (56 FR 46964), the Department published a final rule describing the standards and procedures under which HUD operates the disposition program. The rule is codified at 24 CFR part 291.

Today's rule amends certain provisions of part 291 to allow for greater flexibility in fluctuating market situations and to provide greater opportunities for affordable housing to families and to State and local governments or nonprofit organizations serving low- and moderate-income families. The Department believes these amendments are necessary to implement its policy of revitalizing neighborhoods and communities. In a statement on April 28, 1993, before the Senate Committee on Banking, Housing and Urban Affairs on the anniversary of the Los Angeles riots, HUD Secretary Cisneros emphasized the need to find ways to bring economic lift to poor urban areas and to build a spirit of community within cities across racial and ethnic lines. The Secretary stated that many urban areas are "communities in peril," and that it is time to "pay attention now or pay for problems later in our country's life." The Single Family Property Disposition program is being amended to help make affordable housing a reality for more families everywhere and to help revitalize "communities in peril."

In accordance with its own regulations on rulemaking in 24 CFR part 10, the Department generally publishes a rule for public comment before issuing a rule for effect, unless to do so would be impracticable, unnecessary, or contrary to the public interest. This rule is being published for effect, with the public invited to submit comments that will be taken into consideration in developing a final rule, because the Department believes that delaying implementation of these policies in the urban areas targeted would be contrary to the public interest.

II. Amendments

Single Family Property Disposition (24 CFR Part 291)

The purpose of the property disposition program, which is set out at 24 CFR 291.1(a), is being changed to place greater emphasis on homeownership and improvement of neighborhoods. The amendment provides that the primary objective of the program is to reduce the inventory of acquired properties in a manner that expands homeownership opportunities, strengthens neighborhoods and communities, and ensures a maximum return to the mortgage insurance fund.

This rule contains several amendments that pertain to "revitalization areas," which the rule defines in § 291.5 as urban neighborhoods that are targeted by a city for coordinating affordable housing programs and enhanced supportive services, and where a significant number of HUD-owned properties have been in inventory at least six months. Alternatively, HUD may also target areas as revitalization areas where it has a significant concentration of properties that have been in its inventory for at least six months, whether or not the area has been targeted by a city.

Section 291.100(d) of the rule provides that, in a revitalization area, purchase money mortgages (PMMs) will be available for 85 percent of the purchase price, at current market interest rates, for a period not to exceed five years. The Department will take back PMMs from direct sale purchasers (*i.e.*, governmental entities and private nonprofit organizations) that meet FHA mortgage credit standards and that purchase properties for ultimate resale to owner-occupant purchasers at or below 115 percent of median income.

The Department recognizes that in promulgating the final rule for the Single Family Disposition Program, public commenters urged the use of PMMs as a financing tool for sales to individuals. The Department, while sympathetic to the difficulty of low-income purchasers in obtaining financing, noted in the preamble to the final rule (56 FR 46964, September 16, 1991) that it had determined that "the staff and monetary costs associated with originating and servicing PMMs, combined with the projected losses to the mortgage insurance funds resulting from anticipated high PMM default and foreclosure rates, make the issuance of PMMs prohibitive." This determination is not applicable to this interim rule in

which PMMs will be permitted for purchases by governmental and nonprofit entities. The governmental and nonprofit entities must meet FHA credit standards, and the term of the mortgage will be, as discussed above, for no more than five years, rather than the usual thirty-year term. The Department anticipates that the PMMs will be paid in full in less than five years when the governmental or nonprofit entity sells the property to a qualified individual purchaser. With these safeguards in place, the Department will not encounter the costs of continued servicing, defaults, and foreclosures that it did when it used PMMs to sell acquired properties to individuals. Thus, the Department has determined that the risks to the insurance funds, and the ancillary costs, will be negligible.

Section 291.105(a) is being amended to provide that owner-occupant purchasers will be given a priority in the competitive bid sales method. (The definition of owner-occupant purchaser is being amended to limit it to purchasers who intend to occupy the property as their primary residence. Governmental entities and private nonprofit organizations that purchase properties for use in affordable housing programs are included in a new category of purchaser—direct sale purchaser—added in this rule.) In revitalization areas, the priority for owner-occupant purchasers will be available for up to 30 days and only for properties offered with FHA mortgage insurance. In all other areas, the priority will be available for all properties for a period of time to be set by the Field Office, depending on local circumstances.

The existing rule at 24 CFR 291.105(b) provides that HUD will pay the financing and closing costs in an amount requested by the purchaser up to 6 percent of the purchase price. This rule removes the 6 percent limitation, and provides that the Secretary will determine the maximum limit appropriate for the area. HUD's experience with the program has shown that the amount of closing costs a seller pays fluctuates with market conditions and by geographic area. The removal of the limitation will allow for more flexibility to adjust the amount according to local circumstances. No change is being made with regard to brokers' fees.

The rule also amends § 291.110(a) to allow the discount on direct sale purchases to be determined by the Secretary as appropriate, but not less than 10 percent. The amount of the discount may vary, depending on the location of the property or the number of properties purchased in a single transaction. This change will help organizations who purchase properties for use in homeownership programs, as well as for affordable rental housing and housing for the homeless. A similar change is being made to § 291.110(b) with regard to direct sales to displaced persons who will occupy the property.

Section 291.110(a) is also being amended to set out the procedure by which potential purchasers under the direct sales programs are notified of eligible properties.

The rule also amends § 291.110 to allow for a direct sale to an individual or other entity not otherwise specified in § 291.110. From time to time, situations have arisen in which the Department has deemed it desirable to sell a property directly to an individual (*e.g.*, when a sale failed due to the fault of HUD) but, because the individual did not meet the criteria set out in § 291.110 for direct sales, was unable to do so. Therefore, the rule will provide that authority if a finding is made, in writing, that such a sale would further the goals of the National Housing Act and would be in the best interests of the Secretary.

Section 291.130, Closing, is being amended with regard to extensions of scheduled closings of sales. Under § 291.130(b), 15-day extensions are granted where a scheduled closing cannot be met for reasons beyond the control of the purchaser and HUD has reason to believe that the sale will close within a reasonable time. The rule currently provides that a request for an extension must be accompanied by a non-refundable fee in an amount from $10 to $25 a day. Experience has shown that extensions are often necessary through no fault of the purchaser, and that the policy in many instances works an unnecessary hardship on owner-occupant buyers. Therefore, to provide a measure of relief to its purchasers, while at the same time not unduly penalizing HUD for the delay (since it is the buyer's responsibility to select the funding lender), § 291.130(b) is being amended to permit the initial 15-day extension at no cost to owner-occupant purchasers where documentation indicates that (1) proper and timely loan application was made, (2) the delay is not the fault of the buyer, and (3) mortgage approval is imminent. In addition, this section is being amended to allow extensions at no cost, at any time and to any purchaser, where the delay is the fault of HUD or a direct endorsement lender. Delays of this nature are most commonly associated with the closing of sales involving Section 203(k) financing.

Finally, § 291.135, Forfeiture of earnest money deposits, is being amended with regard to return of earnest money deposits to owner-occupants and direct sale purchasers. The current rule provides that, in the case of insured sales, 100 percent of the earnest money deposit will be returned to an owner-occupant purchaser where HUD (or a Direct Endorsement lender using HUD guidelines) determines that the purchaser is not an acceptable borrower. The amendment provides that, in the case of an uninsured sale, 100 percent of the earnest money deposit made by an owner-occupant purchaser will be returned where the purchaser is pre-approved for mortgage financing in an appropriate amount by a recognized mortgage lender and, despite good faith efforts, is unable to obtain mortgage financing. Such situations may arise where, even though the purchaser has been approved for a loan, the lender will not accept a mortgage on the particular property being purchased. For uninsured sales, where an owner-occupant purchaser has not been preapproved and despite good faith efforts cannot obtain mortgage financing, 50 percent of the earnest money deposit would be returned. For purposes of this rule, "pre-approved" means a commitment has been obtained from a recognized mortgage lender for mortgage financing in a specified dollar amount sufficient to purchase the property. (This definition is being added to § 291.5.)

Occupied Conveyance (24 CFR Part 203)

One of the situations described in 24 CFR 203.670 when HUD will accept conveyance of occupied property for the Single Family Property Disposition program is when it is in the Secretary's interest, the property is habitable, and the remaining occupants meet certain eligibility criteria (§ 203.670(b)(3)). The criteria for determining the Secretary's interest are described in 24 CFR 203.671 as:

(1) Occupancy of the property is essential to protect it from vandalism from time of acquisition to preparation for sale;

(2) The average time in inventory for HUD's unsold inventory in the residential area in which the property is located exceeds six months; and

(3) With respect to multi-unit properties, the marketability of the property would be improved by retaining occupancy of one or more units.

Under the current rule, the Department has no authority to accept a property occupied to avoid the payment of excessive eviction or relocation

expenses required by a local government. These are not frequent occurrences, but these costs have to be paid by the mortgagee and reimbursed by the Department in the claim for insurance benefits. The Department believes that, in the interest of cost-effectiveness, the rule should allow for the acceptance of an occupied property, without requiring that all other eligibility criteria be met by the remaining occupants, where a state or local law requires the payment of high eviction costs or excessive relocation expenses as part of the eviction process. This amendment gives the Department the flexibility necessary to determine whether it is more advantageous to accept conveyance of the property occupied rather than incur the excessive costs that would be generated by an eviction. The occupied conveyance rule at 24 CFR 203.670 and 203.671 is being amended to implement this policy.

A technical correction is also being made to the occupied conveyance regulations at §§ 203.675(b)(4) and 203.676 to conform with an earlier amendment to the rule published on September 16, 1991 (56 FR 46964). That amendment added long-term or permanent illness or injury of an occupant, in addition to temporary illness or injury, as a criterion for accepting conveyance of an occupied property. Sections 203.675(b)(4) and 203.676 are being amended by this rule to conform those sections to the September 16, 1991 amendment.

II. Other Matters

Paperwork Reduction Act

The changes in this rule do not affect the information collection requirements for the Single Family Property Disposition program previously approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act and assigned OMB control numbers 2502–0306.

Executive Order 12291, Federal Regulation

This rule does not constitute a "major rule" as that term is defined in section 1(d) of the Executive Order on Federal Regulation issued by President Ronald Reagan on February 17, 1981. An analysis of the rule indicates that it will not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs of prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

National Environmental Policy Act

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(c) of the National Environmental Policy Act of 1969. The Finding is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development, Room 10276, 451 Seventh Street SW., Washington, DC 20410.

Executive Order 12612, Federalism

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies contained in this rule will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. The rule involves procedures for the sale of HUD-acquired single family homes, and will not affect the relationship between the Federal Government and State and local governments. Therefore, it is not subject to review under the Order.

Executive Order 12606, The Family

The General Counsel, as the Designated Official under Executive Order 12606, The Family, has determined that this rule will not have a significant impact on the family formation, maintenance, and general well-being, and thus is not subject to review under the Order. The rule governs the procedures under which the Department sells acquired single family property. Any effect on the family would be indirect and insignificant.

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule before publication and by approving it certifies that the rule will not have a significant economic impact on a substantial number of small entities. The rule governs the procedures under which the Department sells acquired single family property.

Semiannual Agenda of Regulations

This rule was listed as item number 1460 in the Department's Semiannual Agenda of Regulations published at 58 FR 24382, 24413 on April 26, 1993, under Executive Order 12291 and the Regulatory Flexibility Act.

List of Subjects

23 CFR Part 203

Hawaiian Natives, Home improvement, Loan programs—housing and community development, Mortgage insurance, Reporting and recordkeeping requirements, Solar energy.

24 CFR Part 291

Community facilities, Homeless, Surplus government property, Low and moderate income housing, Mortgages, Lead poisoning, Conflict of interests, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, title 24 of the Code of Federal Regulations is amended to read as follows:

PART 203—SINGLE FAMILY MORTGAGE INSURANCE

1. The authority citation for part 203 continues to read as follows:

Authority: 12 U.S.C. 1709, 1710, 1715b, and 1715u; 42 U.S.C. 3535(d).

2. Section 203.670 is amended by revising paragraph (b)(3) to read as follows:

§ 203.670 Conveyance of occupied property.

* * * * *

(b) * * *

(3) It is in the Secretary's interest to accept conveyance of the property occupied under § 203.671, the property is habitable as defined in § 203.673, and, except for conveyances under § 203.671(d), each occupant who intends to remain in the property after the conveyance meets the eligibility criteria in § 203.674(b).

* * * * *

3. Section 203.671 is amended by adding paragraph (d) as follows:

§ 203.671 Criteria for determining the Secretary's interest.

* * * * *

(d) The high cost of eviction or relocation expenses makes eviction impractical.

§ 203.675 [Amended]

4. Section 203.675(b)(4) is amended by removing the word "temporary" from the first sentence.

5. Section 203.676 is amended by removing the word "temporary" from the second sentence.

PART 291—DISPOSITION OF HUD-ACQUIRED SINGLE FAMILY PROPERTY

6. The authority citation for part 291 is revised to read as follows:

Authority: 12 U.S.C. 1709 and 1715(b); 42 U.S.C. 1441, 1551a, and 3535(d).

7. Section 291.1 is amended by revising paragraph (a) to read as follows:

§ 291.1 Purpose and scope.

(a) *Purpose.* (1) This part governs the disposition of one-to-four family properties that are acquired by HUD or are otherwise in HUD's custody. Detailed policies and procedures that must be followed in specific areas are issued by each HUD field office.

(2) The purpose of the property disposition program is to reduce the inventory of acquired properties in a manner that expands homeownership opportunities, strengthens neighborhoods and communities, and ensures a maximum return to the mortgage insurance fund.

* * * * *

8. Section 291.5 is amended by revising the definition of "Owner-occupant purchaser" and by adding definitions for "Direct sale purchaser", "Pre-approved", "Purchase money mortgage", and "Revitalization area", to read as follows:

§ 291.5 Definitions.

* * * * *

Direct sale purchaser means a State, governmental entity, tribe, or agency thereof; a private nonprofit organization as defined in § 291.405 of this part; tenants in occupancy who are offered the right of first refusal to purchase property under § 291.100(a)(4) of this part; displaced persons as described in § 291.110(b) of this part; and other individuals or entities as described in § 291.110(g) of this part. For purposes of this part, a State means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States. Governmental entities include those with general governmental powers (*e.g.*, a city or county), as well as those with limited or special powers (*e.g.*, public housing agencies).

* * * * *

Owner-occupant purchaser means a purchaser who intends to use the property as his or her principal residence.

Pre-approved means a commitment has been obtained from a recognized mortgage lender for mortgage financing in a specified dollar amount sufficient to purchase the property.

Purchase money mortgage, or *PMM* means a note secured by a mortgage or trust deed given by a buyer, as mortgagor, to the seller, as mortgagee, as part of the purchase price of the real estate.

Revitalization area means an urban neighborhood that is targeted by a city for coordinating affordable housing programs and enhanced supportive services, and where a significant number of HUD-owned properties have been in inventory at least six months. Alternatively, HUD may target urban areas as revitalization areas where it has a significant concentration of properties that have been in inventory at least six months, whether or not targeted by a city.

* * * * *

9. In § 291.100, paragraphs (a)(5), (c), and (d) are revised to read as follows:

§ 291.100 General policy.

(a) * * *

(5) In accordance with § 291.410 of this part, eligible properties may be offered to providers of housing for the homeless before being offered for sale to the general public.

* * * * *

(c) *Method of sale.* (1) Properties are sold on an "as-is" basis, without repairs or warranties. The principal method of sale is the competitive sales procedure, as described in § 291.105 of this part. Where appropriate, the Secretary may utilize any of the other sales procedures described in § 291.110 of this part.

(2) Properties may be sold under the following programs:

(i) *Insured.* A property that HUD believes meets the intent of the Minimum Property Standards (MPS) for existing dwellings (*i.e.*, structurally sound, free of roof leaks, with operable mechanical system) will be offered for sale in "as-is" condition with mortgage insurance available, as described in § 291.115 of this part.

(ii) *Insured with repair escrow.* A property that requires no more than $5,000 for repairs to meet the intent of the MPS, as determined by the Secretary, will be offered for sale in "as-is" condition with mortgage insurance available, provided the mortgagor establishes a cash escrow to ensure the completion of the required repairs, as described in § 291.120.

(iii) *Uninsured.* A property that fails to qualify under either paragraph (c)(2)(i) or (ii) of this section will be offered for sale in "as-is" condition without mortgage insurance available, as described in § 291.125.

(d) *Financing.* (1) Except as provided in paragraph (d)(2) of this section, the purchaser is entirely responsible for obtaining financing for purchasing a property.

(2) In revitalization areas targeted either by HUD or by a city, HUD will take back purchase money mortgages (PMMs) on property purchased by governmental entity or private nonprofit organization direct sale purchasers who purchase property for ultimate resale to owner-occupant purchasers with incomes at or below 115 percent of the area median income. PMMs will be available for 85 percent of the purchase price, at market rate interest, for a period not to exceed five years. Mortgagors must meet FHA mortgage credit standards.

* * * * *

10. In § 291.105, paragraphs (a), (b)(1)(i) and the first sentence of paragraph (c) are revised to read as follows:

§ 291.105 Competitive sales procedure.

(a) *General.* (1) Properties are sold to the general public on a competitive bid basis through local real estate brokers. If a property fails to generate an acceptable bid or offer during the bidding period, it will remain on the market for an extended listing period, as described in paragraph (f) of this section.

(2) In areas designated as revitalization areas, priority will be given to owner-occupant purchasers for properties offered with FHA mortgage insurance for a period of up to 30 days. In all other areas, priority will be given to owner-occupant purchasers for a period of time to be set by the local Field Office, depending on circumstances in the areas.

(b) *Net offer.* (1)(i) If requested by the purchaser in the bid, HUD will pay all or a portion of the financing and loan closing costs and the broker's sales commission, not to exceed the percentage of the purchase price determined appropriate by the Secretary for the area. In no event will the amount for broker's sales commission exceed 6 percent of the purchase price, except for cash bonuses as described in paragraph (b)(1)(ii) of this section. * * *

(c) *Acceptable bid.* HUD will accept the bid producing the greatest acceptable net return to HUD and otherwise meeting the terms of HUD's offering of the property, with priority given to owner-occupant purchasers as described in paragraph (a)(2) of this section. * * *

* * * * *

11. Section 291.110 is amended by revising paragraphs (a) and (b)(1), and

by adding paragraph (g), to read as follows:

§ 291.110 Other sales procedures.

(a) *Direct sales to governmental entities and private nonprofit organizations.* (1) State and local governments, public agencies, and qualified private nonprofit organizations may purchase properties on a direct sale basis, at a discount off the list price determined by the Secretary to be appropriate, but not less than 10 percent, for use in HUD and local housing or homeless programs. The amount of the discount may vary, depending on the area or the number of properties purchased in a single transaction.

(2) (i) Direct sale purchasers, except tenants in occupancy and displacees, under paragraph (a)(1) of this section must designate geographical areas of interest, by ZIP code, to appropriate HUD Field Offices. Upon request, after properties have been offered for sale to owner-occupant purchasers and before they are listed for sale to the general public, Field Offices will notify direct sale purchasers in writing when eligible properties become available in the areas designated by the purchaser. Field Offices will coordinate the dissemination of the information to ensure that where more than one purchaser designate a specific area, those purchasers receive the list of properties at the same time, based on intervals agreed upon between HUD and the purchasers. Properties will be sold on a first come-first served basis.

(ii) Direct sale purchasers must notify HUD of preliminary interest in specific properties within five days of the notification of available properties (where notification is by mail, the five days will begin to run five days after mailing). Those properties in which purchasers express an interest will be held off the market for a ten-day consideration and inspection period. Other properties on the list will continue to be processed for public sale. HUD may limit the number of properties held off the market for a purchaser at any one time, based upon the purchaser's financial capacity as determined by HUD and upon past performance in HUD programs. At the end of the ten-day consideration and inspection period, properties in which no direct sale purchaser has expressed a specific intent to purchase will be offered for sale to the general public. Properties in which a direct sale purchaser expressed an intent to purchase, during the ten-day period, will continue to be held off the market pending receipt of the sales contract. If a sales contract is not received within a time period of up to ten days, as determined by HUD, following expiration of the ten-day consideration and inspection period, and no other direct sale purchaser has expressed an interest, then the property will be offered for sale to the general public.

(b) *Direct sales to displaced persons.* (1) At the discretion of the field office manager, properties eligible for insured financing are offered for direct sale, at a discount off the list price determined by the Secretary to be appropriate, but not less than 10 percent, to displaced persons who will occupy the properties. Properties offered will be only those in the general area in which the displacement is occurring.

* * * * *

(g) *Direct sales to other individuals or entities.* A direct sale may be made to an individual or entity that does not meet any of the categories specified in this section, if a finding is made by the Assistant Secretary for Housing-Federal Housing Commissioner or his or her designee in writing that such a sale would further the goals of the National Housing Act and would be in the best interests of the Secretary.

12. In § 291.130, paragraph (b)(2) is revised and paragraph (b)(3) is added to read as follows:

§ 291.130 Closing.

* * * * *

(b) *Extensions.* * * *

(2) A request for an extension must be in writing, accompanied by the non-refundable fee in an amount not less than $10 a day or more than $25 a day, except as provided in paragraph (b)(3) of this section. The amount charged by a field office depends on circumstances in the area, such as the average holding costs to HUD, the average sales price of properties, and the number of sales that fail to close. Extensions will be granted in 15-day increments only. If a closing occurs in fewer than 15 days, the purchaser credited for any unused portion of the extension fee.

(3) The initial 15-day extension will be provided to owner-occupant purchasers at no cost if documentation is provided indicating that proper and timely loan application was made, that the delayed closing is not the fault of the buyer, and that mortgage approval is imminent. An extension will be provided at any time and to any purchaser at no cost where the delay is the fault of HUD or a direct endorsement lender. In the case of a Section 203(k) loan, an extension of up to 30 days will be granted at no cost where documentation indicates the buyer is not the cause for the delay.

13. Section 291.135 is amended by redesignating paragraph (c)(1)(v) as paragraph (c)(1)(vi), by adding a new paragraph (c)(1)(v), by revising paragraph (c)(2), and by adding a new paragraph (d), to read as follows:

§ 291.135 Forfeiture of earnest money deposits.

* * * * *

(c) * * *

(1) * * *

(v) In the case of an uninsured sale, and the purchaser was pre-approved for mortgage financing in an appropriate amount by a recognized mortgage lender, where the purchaser is unable, despite good faith efforts, to obtain mortgage financing; or

(vi) * * *

(2) In those instances where the purchaser was not pre-approved for mortgage financing by a recognized mortgage lender, and despite good faith efforts by the purchaser there is an inability to obtain a mortgage loan from a recognized mortgage lender, 50 percent of the earnest money deposit will be returned.

(d) *Direct sale purchasers except tenants in occupancy or displacees.* (1) The entire earnest money deposit will be returned to a direct sale purchaser, except tenants in occupancy or displacees, who fails to close where, since the contract of sale was signed:

(i) In the case of an insured sale, HUD (or a Direct Endorsement lender using HUD guidelines) determines that the purchaser is not an acceptable borrower; or

(ii) For other good cause, as determined by the field office.

(2) Direct sale purchaser who are tenants in occupancy or displacees are subject to the earnest money forfeiture rules that apply to owner-occupant purchasers, as described in paragraph (c) of this section.

Dated: September 24, 1993.

Nicholas P. Retsinas,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 93–25629 Filed 10–19–93; 8:45 am]

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