proposed rules

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Part 1304]

RECORDS AND REPORTS OF REGISTRANTS

Records for Manufacturers

Regulations of the Drug Enforcement Administration require, in § 1304.22 of Title 21 of the Code of Federal Regulations, that manufacturers of controlled substances maintain records which show the quantity of controlled substances actually manufactured or actually used, to be used, or capable of use in manufacturing controlled or non-controlled substances.

These records, while revealing the theoretical and actual yield of controlled substances produced by the manufacturing process, as determined by the manufacturer, fail to provide DEA with any information upon which it can independently determine such yields.

Lacking this information, DEA cannot establish whether amounts of controlled substances produced in fact are more than what is reported to DEA as the actual yield.

Such discrepancies could occur with DEA unaware of the existence of any such unreported amounts of controlled substances produced, or their disposition. That such amounts could exist and be diverted is a real possibility which requires DEA, in its effort to identify diversion, to establish some means for determining that the yield of a controlled substance manufacturing process corresponds with the theoretical yield, which the process and the materials used therein, are designed to produce.

Therefore, in view of the foregoing, and pursuant to the authority vested in the Attorney General by sections 301 and 501(b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 821, 871(b)), and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 28 of the Code of Federal Regulations (See 38 FR 18380, July 2, 1973), and redelegated to the Deputy Administrator of the Drug Enforcement Administration by 28 CFR 0.104 [Appendix to Subpart R] Sec. 6(g), the Deputy Administrator of the Drug Enforcement Administration hereby proposes that Part 1304 of Title 21 of the Code of Federal Regulations be amended as follows:

Existing paragraphs (a) (2) through (9) are to be renumbered as paragraphs (a) (3) through (10), and a new paragraph (a) (2) is to be added, to read as set forth below.

§ 1304.22 Records for manufacturers.

(a) * * *

(2) For each batch, the identity, amount, and percent purity of each ingredient used in manufacturing each controlled substance;

* * * * *

All interested parties are invited to submit their comments and objections in writing regarding this proposal. Comments and objections should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, United States Department of Justice, Washington, D.C. 20537, Attention: DEA Federal Register Representative and must be received no later than February 11, 1976.

Dated: December 24, 1975.

JERRY N. JENSON,
Deputy Administrator,
Drug Enforcement Administration.

[FR Doc.76-557 Filed 1-7-76;8:45 am]

DEPARTMENT OF THE TREASURY

Customs Service

[19 CFR Part 12]

SPECIAL CLASSES OF MERCHANDISE

Importation of Motor Vehicles and Motor Vehicle Equipment; Extension of Time

Correction

In FR Doc. 75-35040, appearing at page 59745, in the issue for Tuesday, December 30, 1975, the second paragraph should read as set out below:

"Requests have been received for an extension of the time for the submission of comments. Therefore, the period for submission of data, views, or arguments with respect to the cited amendments is extended to January 22, 1976.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 338, 339, 340]

[Docket No. 75-N-0244]

OVER-THE-COUNTER DRUGS

Proposal To Establish Monographs for OTC Nighttime Sleep-Aid, Daytime Sedative, and Stimulant Products

Correction

In FR Doc. 75-32774, appearing on page 59447 in the issue of Monday, December 8, 1975 make the following changes:

1. On page 57298, the second column, in the first complete paragraph, the second word in the eighth line should read "extracellular".

2. On page 57298, the third column, the sixth complete paragraph; in the third line the word "and" should have read "an", and in the fourth line the word "Larges" should have read "Larger".

3. On page 57299, in the first column, the second complete paragraph, the ninth line should have read "logical tests showed that 44 percent (6 subjects)".

4. On page 57300, in the third column, paragraph "b.", the first word in each of the third and fourth lines was mispelled. The correct spelling is "hydrobromide".

5. On page 57301, in the third column, the fifth paragraph, in the tenth line the fourth word should have been spelled "medullary".

6. On page 57302, in the third column, second paragraph, in the second line the last word should have been preceded with an "s".

7. On page 57305, in the second column, the first whole paragraph, the second word in the sixteenth line should have read "of".

8. On page 57307, in the second column, the sixth paragraph should have read: "(15) Cappe, B. E. and I. M. Tallin, "Recent Advances In Obstetric Analgesia,", *"Journal of the American Medical Association,* 154: 377-379, 1954."

9. On page 57309, the third column; in the first complete paragraph, eleventh line, the first word should have read "hydramine". In the third complete paragraph, the seventh word in the first sentence should have read "effects".

10. On page 57310, the second column, after the heading "References", the first word in the second line should have read "Antihistaminic".

11. On page 57312, the second column, the second paragraph after the heading "References", in the first line the word "Propandiol" was misspelled. In the third column the last line should have read "Methoxybenzyl-N-Dimethyl-aminoethyl al-".

12. On page 57316, in the second column, fifth line, the fourth word should have read "as".

13. On page 57324, in the first column, under "REFERENCES" the footnote to "(1)" should have read "3" and refers to the note on page 57310.

14. On page 57325, in the 36th line the fourth word was misspelled, it should have read "incidence".

15. On page 57327, in the third column, 16th line the second word should have read "an".

16. On page 57328, the first column, in the last line of the "Authority" the first number should have read "553".

17. On page 57328, the second column, the last line of § 339.3 should have read "sional simple nervous tension.".

Social Security Administration

[20 CFR Part 405]

FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Conditions of Participation; Skilled Nursing Facilities; Withdrawal of Notice of Proposed Rule Making

On February 11, 1975, there was published in the FEDERAL REGISTER (40 FR 6369) a Notice of Proposed Rule Making which set forth a proposed technical amendment to Subpart K of Regulations No. 5 relating to the conditions of participation for skilled nursing facilities. The proposed amendment would have effected a technical change in the Medicare regulations to correspond to a proposed revision of Part 249 of the Social and Rehabilitation Service regulations (45 CFR Part 249) which was also published on February 11, 1975, (40 FR 6368). The proposed Medicare regulation would have provided that, with respect to skilled nursing facilities participating only in the Medicaid program, the Secretary of Health, Education, and Welfare (rather than the State survey agency as at present) would grant waivers of specific provisions of the standards of the American National Standards Institute regarding the usability of facilities by handicapped persons and would permit variations in the standards regarding room size and the number of patients per room.

Under the proposed amendment, the Secretary would thus have had the authority to grant waivers where the skilled nursing facility is participating in the Medicare program, the Medicaid program, or both.

Interested parties were given 30 days within which to submit data, views, and arguments. Three comments were received in response to the notice of proposed rule making. Two comments were in favor of the State agency's retaining the waiver authority. The third comment favored transfer of waiver authority to the Secretary.

Since many of the comments received in response to the proposed amendment to 45 CFR Part 249 published at 40 FR 6368 were unfavorable, it was withdrawn (see 40 FR 51474, November 5, 1975). Accordingly, the proposed amendment to 20 CFR Part 405 published at 40 FR 6369, which was primarily for the purpose of consistency, is hereby withdrawn. The proposed amendment and the withdrawal thereof will have no effect on skilled nursing facilities participating under title XVIII or both under title XVIII and title XIX, since for both categories, the Secretary has the authority under existing regulations to issue the subject waivers (see 20 CFR 405.1134 (c) and (e)).

(Secs. 1102 and 1871 of the Social Security Act, 49 Stat. 647, as amended, 79 Stat. 331; 42 U.S.C. 1302 and 1395 hh.)

(Catalog of Federal Domestic Assistance Program No. 13.800, Health Insurance for the Aged and Disabled—Hospital Insurance.)

Dated: December 11, 1975.

J. B. CARDWELL,
Commissioner of Social Security.

Approved: January 2, 1976.

MARJORIE LYNCH,
Acting Secretary of Health, Education, and Welfare.

[FR Doc.76-521 Filed 1-7-76;8:45 am]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Federal Insurance Administration

[24 CFR Part 1905]

[Docket No. R-76-367]

NATIONAL INSURANCE DEVELOPMENT PROGRAM

Notice of Proposed Rule Making

Pursuant to Title XI and Title XII of the National Housing Act (added by the Urban Property Protection and Reinsurance Act of 1968, 12 U.S.C. 1749 bbb–1749 bbb–21), 5 U.S.C. 553, as amended by the National Insurance Development Act of 1975 (Pub. L. 94–13, 89 Stat. 68, 12 U.S.C. 1749 bbb Note), and delegation of authority by the Secretary of Housing and Urban Development (34 FR 2680, February 27, 1969), the Federal Insurance Administrator is considering the revision of Part 1905 as set forth below. The revision is a result of a recent examination, by the Department, of its own role in consumer protection activities and follows the spirit of President Ford's April 17, 1975, letter to the Congress stressing the importance of assuring that consumer interests "receive full consideration in all Government actions." The President directed that each agency and Department undertake a review of its policies and procedures as they affect consumer representation in agency decisionmaking and this revision is in furtherance of the Department's commitment to a primary goal to assure that the rights and interests of consumers are fully considered and duly respected.

Section 1102 of the Urban Property Protection and Reinsurance Act of 1968 has, as its purpose, "to encourage and assist the various State insurance authorities and the property insurance industry to develop and carry out statewide programs which will make necessary property insurance coverage against the fire, crime, and other perils more readily available for residential, business, and other properties meeting reasonable underwriting standards," which purpose is carried out through statewide plans requiring insurance industry cooperation in all-industry insurance placement facilities to assure Fair Access to Insurance Requirements (FAIR Plans) pursuant to Sections 1211 et seq. of the National Insurance Development Program.

Interested persons are invited to participate in the making of the proposed rule by submitting such written comments or suggestions as they may desire. Communications should identify the subject matter by the above title and area affected and should be submitted to the Rules Docket Clerk, Office of General Counsel, Department of Housing and Urban Development, Room 10245, 451 Seventh Street SW., Washington, D.C. 20410.

All communications received on or before February 9, 1976, will be considered by the Administrator before taking action on the proposal. The proposals in this notice may be changed in the light of the comments received. A copy of each submission will be available for public inspection during business hours at the above address.

Accordingly, in furtherance of the goals of such FAIR Plans and in order to implement the Department's consumer goals, Subchapter A of Chapter X of Title 24 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1905—STATEWIDE "FAIR" PLANS

1. § 1905.13 is added to read as follows:

§ 1905.13 Notice to policyholders.

(a) Each participating or cooperating insurer offering insurance pursuant to this program (12 U.S.C. 1749bbb–1749bbb–21) shall provide a notice to all FAIR Plan policies issued or renewed on and after April 1, 1976, containing the following information:

(1) Authority for issuance of policy.

(2) FAIR Plan name, address, and telephone numbers.

(3) State Insurance Department addresses and telephone numbers.

(4) Federal Insurance Administrator's address and telephone number.

(b) Compliance with the requirements of paragraph (a) above will be satisfied provided the participating or cooperating insurer complies with a format of notice as designated by the Administrator; such notices shall, as a minimum, include the following information employing the same terms or substantially similar terms subject to prior approval by the Administrator.

Dear Policyholder: The attached FAIR Plan Insurance Policy, or renewal thereof, has been issued to you by the FAIR Plan in cooperation with your State Insurance Authority and the Federal Insurance Administration of the United States Department of Housing and Urban Development. The policy is serviced generally by the statewide FAIR Plan, as listed at the end of this Notice. The FAIR Plan or your insurance agent will assist you if you need to report a loss or if you have any questions pertaining to the premium charged or the scope of the coverage afforded under the policy. In addition, your State Insurance Department and the Federal Insurance Administration (FIA) is ready to be of assistance to you in these matters, if the FAIR Plan or agent cannot help you. Moreover, since the FAIR Plan Program is intended to provide you with the highest caliber of service, FIA would welcome any suggestions you may have for improving the program. Please do not hesitate to write, for assistance, to:

(1) FAIR Plan: [Name, Address, Telephone Number].