

expenditure rates of programs under the Act.

Regulatory Impact

This proposed rule is a technical amendment conforming to changes in JTPA reporting requirements. As such, it does not have the financial or other impact to make it a major rule, and therefore, the preparation of a regulatory impact analysis is not necessary. See Executive Order No. 12291, 3 CFR, 1981 Comp., p. 127.

The Department of Labor has notified the Chief Counsel for Advocacy, Small Business Administration, and made the certification pursuant to 5 U.S.C. 605(b) that the proposed rule will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act. The reports under the rule are to be made by States, which are not small entities as defined under the Regulatory Flexibility Act.

Paperwork Reduction Act

This proposed rule changes an information collection requirement previously approved by the Office of Management and Budget pursuant to 44 U.S.C. 3501 *et seq.* The applicable reporting requirement for grantees would no longer be limited to an annual period. As would be permitted by the proposed rule, the Department of Labor is requesting OMB's approval pursuant to the Paperwork Reduction Act, for the report to be made semiannually.

Catalog of Federal Domestic Assistance Number

This program is listed in the *Catalog of Federal Domestic Assistance* at No. 17.250, "Job Training Partnership Act (JTPA)".

List of Subjects in 20 CFR Part 629

Grant programs, Labor, Manpower training programs.

Proposed Rule

Accordingly, Part 629 of Chapter V of Title 20, Code of Federal Regulations is proposed to be amended as follows:

PART 629—[AMENDED]

1. The authority citation for Part 629 continues to read as follows:

Authority: Job Training Partnership Act, Sec. 169, Pub. L. 97-300, 96 Stat. 1322 (29 U.S.C. 1501 *et seq.*).

2. Section 629.36 is revised to read as follows:

§ 629.36 Reports required.

The Governor shall report to the Secretary pursuant to instructions

issued by the Secretary. Reports shall be required by the Secretary no more frequently than semiannually. Reports shall be submitted to the Secretary within 45 calendar days after the end of the report period. (Section 165(a)(2))

Signed at Washington, DC, this 3rd day of February 1986.

Roger D. Semerad,
Assistant Secretary for Employment and Training.

[FR Doc. 86-2827 Filed 2-6-86; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606, 610, and 640

[Docket No. 82N-0163]

Biological Products; Blood and Blood Derivatives; Implementation of Efficacy Review

Correction

In FR Doc. 85-30007 beginning on page 52602 in the issue of Tuesday, December 24, 1985, make the following corrections;

1. On page 52720, third column, in § 606.151 (b), third line, "of" should read "or".

2. On page 52721, first column, in § 610.53 (a), in the table, second column, third line from the bottom, "21 days" should read "35 days".

3. On page 52722, second column, in § 640.65 (b)(2)(i), first line, "Expect" should read "Except".

4. On page 52722, third column, in § 640.84(b), second line, "NO" should read "DO". Also, in § 640.84 (c), second line, "of" should read "or".

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposed Placement of Quazepam and Midazolam Into Schedule IV

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice is a proposed rule to place the benzodiazepine drugs, quazepam and midazolam, into Schedule IV of the Controlled Substances Act (21 U.S.C. 801 *et seq.*). The Administrator of the Drug Enforcement Administration has

received recommendations from the Department of Health and Human Services that quazepam and midazolam be controlled in Schedule IV.

DATE: Comments must be submitted on or before March 10, 1986.

ADDRESS: Comments and objections should be submitted to the Administrator, Drug Enforcement Administration, 1405 I Street, NW., Washington, DC 20537, Attention: DEA Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION:

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control; Narcotics, Prescription drugs.

The Administrator of the Drug Enforcement Administration received a letter dated December 18, 1985 regarding quazepam and another letter dated January 13, 1986 regarding midazolam from the Acting Assistant Secretary for Health, on behalf of the Secretary of the Department of Health and Human Services, recommending that each substance be placed into Schedule IV of the Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801-966)). Enclosed with each letter from the Acting Assistant Secretary was a scientific and medical evaluation which listed the factors which the Act requires the Secretary to consider, and summarized the matters considered by the Acting Assistant Secretary in recommending the control of quazepam and midazolam under the Controlled Substances Act. In his letters, the Acting Assistant Secretary requested that the Drug Enforcement Administration delay the publication of the proposed rulemaking until notification of final approval by the FDA. The Drug Enforcement Administration has been advised that the NDA approval letters have been forwarded to the sponsors of each of the drugs in question, and that FDA recommends that the rulemaking procedures be initiated.

This proposed rulemaking is published based upon the letters received from the Food and Drug Administration and the Acting Assistant Secretary for Health that the NDA's for quazepam and midazolam have been approved. The final rule in this matter will be issued when the Administrator receives formal notification from the

Assistant Secretary for Health or the Food and Drug Administration that the NDA's for quazepam and midazolam have received final approval from the Food and Drug Administration.

The factors considered by the Secretary for each of the drugs, quazepam and midazolam, were:

- (1) Its actual or relative potential for abuse;
- (2) Scientific evidence of its pharmacological effect, if known;
- (3) The state of current scientific knowledge regarding the drug (or other substance);
- (4) Its history and current pattern of abuse;
- (5) The scope, duration and significance of abuse;
- (6) What, if any, risk to the public health;
- (7) Its psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under this title.

Relying on the scientific and medical evaluations and the recommendations of the Acting Assistant Secretary for Health, received in accordance with section 201(f) of the Act (21 U.S.C. 811(f)), the Administrator of the Drug Enforcement Administration, pursuant to sections 201(a) and 201(b) of the Act, (21 U.S.C. 811(a) and 811(b)), finds that:

- (1) Based on information now available, quazepam and midazolam each appear to have a low potential for abuse relative to the drugs or other substances currently listed in Schedule III.
- (2) Quazepam and midazolam, upon final approval of each new drug application by the Food and Drug Administration, will each have currently accepted medical uses in treatment in the United States.
- (3) Abuse of either quazepam or midazolam may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

PART 1308—[AMENDED]

Therefore, under the authority vested in the Attorney General by section 201(a) of the Act (21 U.S.C. 811(a)) and delegated to the Administrator of the Drug Enforcement Administration by regulations of the Drug Enforcement Administration by regulations of the Department of Justice (28 CFR Part 0.100), the Administrator hereby proposes to amend 21 CFR 1308.14(c) to read as follows:

1. The authority citation for 21 CFR Part 1308 continues to read as follows:

Authority: 21 U.S.C. 811(a).

2. Section 1308.14(c) would be revised to read as follows:

§ 1308.14 Schedule IV.

* * * * *

(c) * * *

(1) Alprazolam.....	2882
(2) Barbitol.....	2145
(3) Bromazepam.....	2748
(4) Camazepam.....	2749
(5) Chloral betaine.....	2460
(6) Chloral hydrate.....	2465
(7) Chlordiazepoxide.....	2744
(8) Clobazam.....	2751
(9) Clonazepam.....	2737
(10) Clorazepate.....	2768
(11) Clatiazepam.....	2752
(12) Cloxazolam.....	2753
(13) Delorazepam.....	2754
(14) Diazepam.....	2765
(15) Estazolam.....	2756
(16) Ethchlorvynol.....	2540
(17) Ethinamate.....	2545
(18) Ethyl loflazepats.....	2758
(19) Fludiazepam.....	2759
(20) Flunitrazepam.....	2763
(21) Flurazepam.....	2767
(22) Halazepam.....	762
(23) Haloxazolam.....	2771
(24) Ketazolam.....	2772
(25) Loprazolam.....	2773
(26) Lorazepam.....	2885
(27) Lormetazepam.....	2774
(28) Mebutamate.....	2800
(29) Medazepam.....	2836
(30) Meprobamate.....	2820
(31) Methohexital.....	2264
(32) Methylphenobarbital (mephobarbital).....	2250
(33) Midazolam.....	2884
(34) Nimetazepam.....	2837
(35) Nitrazepam.....	2834
(36) Nordiazepam.....	2838
(37) Oxazepam.....	2835
(38) Oxazolam.....	2839
(39) Paraldehyde.....	2585
(40) Petrichloral.....	2591
(41) Phenobarbital.....	2285
(42) Pinazepam.....	2883
(43) Prazepam.....	2764
(44) Quazepam.....	2881
(45) Temazepam.....	2925
(46) Triazepam.....	2886
(47) Triazolam.....	2887

* * * * *

Interested persons are invited to submit their comments or objections in writing regarding this proposal. If a person believes that one or more issues raised by him warrant a hearing, he should so state and summarize the reasons for his belief. Comments and objections should be submitted to the Administrator, Drug Enforcement Administration, 1405 I Street, NW., Washington, DC 20537, Attention: DEA Federal Register Representative.

In the event comments, objections, or requests for a hearing received in response to this proposal raise one or more issues which the Administrator finds warrant a hearing, the Administrator shall order a public

hearing by notice in the Federal Register summarizing the issues to be heard and setting the time for the hearing (which will not be less than 30 days after the date of the order).

If no objections presenting grounds for a hearing on this proposal are received within the time limitation or if interested parties waive or are deemed to have waived their opportunity for a hearing or to participate in a hearing, the Administrator, after giving consideration to written comments and objections, will issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the control of quazepam or midazolam, as proposed herein, will have no significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). These scheduling actions relate to the proposed initial control of drugs not previously approved for marketing in the United States.

In accordance with the provisions of section 201(a) of the Controlled Substances Act (21 U.S.C. 811(a)), this proposal to place each substance, quazepam and midazolam, into Schedule IV is a formal rulemaking "on the record after opportunity for a hearing." Such formal proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and as such have been exempted from the consultation requirements of Executive Order 12291.

Dated: February 3, 1986.

John C. Lawn,
Administrator, Drug Enforcement Administration.

[FR Doc. 86-2732 Filed 2-6-86; 8:45 am]

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28 CFR Part 16

[AAG/A Order No. 5-86]

Exemption of Records Systems Under the Privacy Act

AGENCY: Department of Justice.

ACTION: Proposed rule.

SUMMARY: The Department of Justice proposes to exempt a Privacy Act system of records from subsections (c)(3) and (4); (d); (e)(1), (2) and (3), (e)(4)(G) and (H), (e)(5); and (g) of the Privacy Act, 5 U.S.C. 552a. This system is the "Declassification Review System (JUSTICE/OLP-004)." Information in this system relates to official Federal investigations and matters of law enforcement. The exemption is needed