for policy implications and developing amendments to legislative proposals to further short- and intermediate-range policy objectives.

(e) *Representation.* Representing the Assistant Secretary in meetings with agriculture, industry, and consumer groups to discuss the economic impact of existing and proposed Department policies.

§ 3900.4 Authority to act for the Director.

When the Director is absent or temporarily unavailable, the Staff Statistician is authorized to act for the Director.

PART 3901—AVAILABILITY OF INFORMATION TO THE PUBLIC

Sec.
3901.1 General.
3901.2 Public inspection, copying and indexing.
3901.3 Requests for records.
3901.4 Denials.
3901.5 Appeals.

Authority: 5. U.S.C. 301 and 552; 7 CFR 1.1-1.19 and Appendix A.

§ 3901.1 General

This part is issued in accordance with the regulations of the Secretary of Agriculture in §§ 1.1 through 1.19 of this title and Appendix A thereto, implementing the Freedom of Information Act (FOIA) (5 U.S.C. 552), and governs the availability of records of the Economic Analysis Staff (EAS) to the public.

§ 3901.2 Public inspection, copying, and indexing.

5 U.S.C. 52(a)(2) requires that certain materials be made available for public inspection and copying and that a current index of these materials be published quarterly or otherwise be made available. EAS does not maintain any materials within the scope of these requirements.

§ 3901.3 Request for records.

Requests for records of EAS shall be made in accordance with § 1.6 (a) and (b) of this title and addressed to: Economics Agencies FOIA Officer, Economics Management Staff, USDA, Room 4310, South Building, 12th and Independence Avenue, SW., Washington, DC 20250. This official in delegated authority to make determinations regarding such requests in accordance with § 1.3(b) of this title.

§ 3901.4 Denials.

If the Economics Agencies FOIA Officer determines that a requested record is exempt from mandatory disclosure and that discretionary release would be improper, the Economics Agencies FOIA Officer shall give written notice of denial in accordance with § 1.7(a) of this title.

§ 3901.5 Appeals.

Any person whose request is denied shall have the right to appeal such denial. Appeals shall be in accordance with § 1.6(e) of this title and addressed to the Director, Economic Analysis Staff, U.S. Department of Agriculture, Washington, DC 20250.

Done at Washington, DC, this 11th day of March 1987.

Keith J. Collins,

Director, Economic Analysis Staff.

[FR Doc. 87-6810 Filed 3-26-87; 8:45 am]

BILLING CODE 3410-19-M

FEDERAL HOME LOAN BANK BOARD

12 CFR Parts 546, 552, 563, 572a and 574

[No. 87-306]

Acquisitions of Control of Insured Institutions and Delegated Merger Approvals; Technical Corrections

Dated: March 18, 1987.

AGENCY: Federal Home Loan Bank Board.

ACTION: Final rule; technical corrections.

SUMMARY: The Federal Home Loan Bank Board ("Board"), as operating head of the Federal Savings and Loan Insurance Corporation ("FSLIC"), is making technical and conforming corrections to its regulations governing acquisitions of control of insured institutions and delegated merger approvals adopted by the Board on November 8, 1985, Board Res. Nos. 85-1005, 85-1006; 50 FR 48685, 48725 (Nov. 26, 1985), and to other regulations governing consolidations and combinations of insured institutions.

EFFECTIVE DATE: March 27, 1987.

FOR FURTHER INFORMATION CONTACT: Kevin A. Corcoran, Staff Attorney, (202) 377-6203, Neil R. Crowley, Deputy Director for Corporate, (202) 377-6962, or Julie L. Williams, Deputy General Counsel (202) 377-6459; Corporate and Securities Division, Office of General Counsel, Federal Home Loan Bank Board, 1700 G Street NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: The Board, as operating head of the FSLIC, is making technical and conforming corrections to its regulations governing acquisitions of control of insured institutions and consolidations and combinations of insured institutions. On November 8, 1985, the Board adopted extensive amendments to its regulations implementing the Change in Savings and Loan Control Act, 12 U.S.C. 1730(q) ("Control Act") and the acquisition provisions of the Savings and Loan Holding Company Amendments of 1967, 12 U.S.C. 1730a, ("Holding Company Act") in Resolution No. 85-1005. 50 FR 48685 (Nov. 26, 1985). Also on November 8, 1985, the Board adopted amendments to its regulations governing delegations of authority for processing applications involving interim institutions, mergers, consolidations, bulk transfers and other transfers of assets and liabilities in Resolution No. 85-1006. 50 FR 48725 (Nov. 26, 1985). Adoption of the two Resolutions resulted in complex amendments to numerous Board regulations.

The Board has become aware of several typographical errors, missing words, and potentially confusing punctuation in the regulations as published in the **Federal Register** on November 26, 1985. Some of these errors might confuse a reader into thinking that pertinent words or phrases have been inadvertently omitted. In addition, the Board is aware of several outdated regulatory citations in its regulations that should be corrected. Accordingly, the Board is taking this opportunity to make technical corrections in these respects.

In addition, the amendments adopted today at 12 CFR 546.2(d), 552.13(i)(3), 552.13(j)(3), and 563.22(d), regarding procedures for formation of interim institutions update the citations in those regulations from Part 584 to Part 574. These conforming amendments were unintentionally omitted from Board Resolution No. 85-1005, and are necessary because the regulations currently cite regulations that no longer exist. The effect of these amendments is to clarify the permissibility of certain procedures, previously available only in connection with mergers involving interim institutions created by companies, to be used in the context of mergers involving interim institutions created by other persons. The Board, in Board Resolution No. 85-1005, specifically mentioned the clarification, streamlining and expediting of various application procedures and the provision of a uniform type of public notice for holding company applications and change in control notices as being among its purposes in amending its regulations governing the acquisition of control of insured institutions. Accordingly, this correction regarding the procedures pertaining to interim institutions in the context of an

acquisition of control of an insured institution is entirely consistent with the Board's purposes in implementing Part 574.

The Board also is amending 12 CFR 574.7(g)(1)(iii), which, *inter alia*, sets forth a rebuttable presumption that an acquiror may fail to satisfy the managerial resources and future prospects tests of 12 CFR 574.7(c) or the integrity test of 12 CFR 574.7(d)(4) if a management official of the acquiror was a management official or director of a company or insured institution that was placed into receivership, conservatorship, or was placed in a management consignment program, or was liquidated during his tenure or within two years thereafter. The discussion of this presumptive disqualifier in Resolution No. 85–1005 clearly indicated that the presumptive disqualifier also was intended to be applicable to any management official of the acquiror who was a controlling shareholder of such an entity. The presumptive disqualifier as originally stated, however, inadvertently omitted mention of controlling shareholders, and this amendment corrects that oversight.

Because these changes are either nonsubstantive or relieve restrictions currently in effect, the Board finds that observance of the notice and comment procedure pursuant to 5 U.S.C. 553(b) and 12 CFR 508.11 and the 30-day delay of effective date pursuant to 5 U.S.C. 553(d) and 12 CFR 508.14 is unnecessary and contrary to the public interest.

List of Subjects in 12 CFR Parts 546, 552, 563, 572a and 574

Administrative practice and procedure, Bank deposit insurance, Holding companies, Investments, Reporting and recordkeeping requirements, Savings and loan associations, Securities.

Accordingly, the Board hereby amends Parts 546 and 552, Subchapter C, Parts 563, 572a and 574, Subchapter D, Chapter V, Title 12, Code of Federal Regulations, as set forth below.

SUBCHAPTER C—FEDERAL SAVINGS AND LOAN SYSTEM

PART 546—MERGER, DISSOLUTION, REORGANIZATION, AND CONVERSION

1. The authority citation for Part 546 continues to read as follows:

Authority: Secs. 2, 5, 48 Stat. 128, 132, as amended (12 U.S.C. 1462, 1464); secs. 401–403, 405–407, 48 Stat. 1255–1257, 1259–1260, as amended (12 U.S.C. 1724–1726, 1728–1730); Sec. 406, 82 Stat. 5, as amended (12 U.S.C. 1730a); Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943–1948 Comp., p. 1071.

2. Amend § 546.2 by revising paragraphs (d)(3) and (h)(1)(i) to read as follows:

§ 546.2 Procedure; effective date.

* * * * *

(d) * * *

(3) This paragraph (d) shall not apply to mergers involving an interim Federal association or an interim state institution if the resulting institution is immediately acquired pursuant to Part 574 of this chapter, in which case the procedures set forth in § 574.6 of this chapter shall apply.

* * * * *

(h)(1) * * *

(i) The resulting association requests the granting of supervisory forbearances;

* * * * *

PART 552—INCORPORATION, ORGANIZATION, AND CONVERSION OF FEDERAL STOCK ASSOCIATIONS

3. The authority citation for Part 552 continues to read as follows:

Authority: Sec. 5A, 47 Stat. 727, as added by sec. 1, 64 Stat. 256, as amended (12 U.S.C. 1425a); secs. 2, 5, 48 Stat. 128, 132, as amended (12 U.S.C. 1462, 1464); secs. 401–403, 405–407, 48 Stat. 1255–1257, 1259–1260, as amended (12 U.S.C. 1724–1726, 1728–1730); sec. 406, 82 stat. 5, as amended (12 U.S.C. 1730a); Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943–1948 Comp., p. 1071.

4. Amend § 552.13 by revising paragraphs (i)(3) and the first sentence of paragraph (j)(3) to read as follows:

§ 552.13 Combinations involving Federal stock associations.

* * * * *

(i) *Notice.* * * *

(3) *Procedure.* Processing of an application under this section shall follow the procedures set forth in this paragraph (i) and in §§ 543.2 (e) and (f) of this subchapter, except for applications in which the resulting institution is immediately acquired pursuant to Part 574 of this Chapter, in which case the procedures set forth in § 574.6 of this Chapter shall apply.

* * * * *

(j) Approval by stockholders. * * *

(3) *Exceptions for certain combinations involving an interim institution.* Stockholders of a Federal stock association need not authorize by a two-thirds affirmative vote combinations involving an interim Federal association or interim state institution when the resulting Federal stock association is acquired pursuant to Part 574 of this Chapter. * * *

* * * * *

5. Amend § 552.14 by revising the last sentence of paragraph (b) to read as follows:

§ 552.14 Dissenter and appraisal rights.

* * * * *

(b) * * * "Qualified consideration" means cash, shares of stock of any association or corporation which at the effective date of the combination will be listed on a national securities exchange or quoted on NASDAQ, or any combination of such shares of stock and cash.

* * * * *

SUBCHAPTER D—FEDERAL SAVINGS AND LOAN INSURANCE CORPORATION

PART 563—OPERATIONS

6. The authority citation for Part 563 continues to read as follows:

Authority: Sec. 1, 47 Stat. 725, as amended (12 U.S.C. 1421 *et seq.*); sec. 5A, 47 Stat. 727, as added by sec. 1, 64 Stat. 256, as amended (12 U.S.C. 1425a); sec. 5B, 47 Stat. 727, as added by sec. 4, 80 Stat. 824, as amended (12 U.S.C. 1425b); sec. 17, 47 Stat. 736, as amended (12 U.S.C. 1437); sec. 2, 48 Stat. 128, as amended (12 U.S.C. 1462); sec. 5, 48 Stat. 132, as amended (12 U.S.C. 1464); secs. 401–407, 48 Stat. 1255–1260, as amended (12 U.S.C. 1724–1730); sec. 408, 82 Stat. 5, as amended (12 U.S.C. 1730a); Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943–1948 Comp., p. 1071.

7. Amend § 563.22 by revising the first sentence of paragraph (b); and by revising paragraphs (d) and (e)(1)(i) to read as follows:

§ 563.22 Merger, consolidation, purchase or sale of assets, or assumption of liabilities.

* * * * *

(b) No insured institution may at any time make a transfer, as defined in § 571.5(a) of this Subchapter, of assets or savings account liabilities without application to and approval by the Corporation: *Provided,* that any insured institution that must receive approval for such transfer from the Federal Deposit Insurance Corporation pursuant to section 5(o)(2)(D) of the Home Owners' Loan Act, as amended, 12 U.S.C. 1464(o)(2)(D), shall not be subject to approval by the Corporation under this paragraph. * * *

* * * * *

(d) The requirements of paragraph (c) of this section do not apply to any merger, consolidation, purchase of assets, or assumption of liabilities: (1) Authorized by the Corporation to be instituted for supervisory reasons, or (2) involving an interim Federal association or an interim state-chartered institution if the resulting institution is immediately acquired pursuant to Part 574 of this

chapter, in which case the procedures set forth in § 574.6 of this chapter shall apply.

(e)(1) * * *

(i) The resulting institution requests the granting of supervisory forbearances;

* * * * *

PART 572a—VOLUNTARY ASSISTED-MERGER PROGRAM

8. The authority citation for Part 572a is revised to read as follows:

Authority: Secs. 2, 5, 48 Stat. 128, 132, as amended (12 U.S.C. 1462, 1464); secs. 401–403, 405–407, 48 Stat. 1255–1257, 1259–1260, as amended (12 U.S.C. 1724–1726, 1728–1730); Reorg. Plan No. 3 of 1947, 3 CFR, 1943–1948 Comp., p. 1071.

9. Amend § 572a.5 by revising the second sentence of paragraph (c)(5) to read as follows:

§ 572a.5 Actions by Principal Supervisory Agent.

* * * * *

(c) *Approvals.* * * *

(5) * * * In connection with a merger or acquisition so approved, a Principal Supervisory Agent may grant the resulting institution supervisory forbearances in accordance with supervisory procedures memoranda issued by ORPOS; and

* * * * *

PART 574—ACQUISITION OF CONTROL OF INSURED INSTITUTIONS

10. The authority citation for Part 574 continues to read as follows:

Authority: Sec. 407, 48 Stat. 1260, as amended (12 U.S.C. 1730); and Sec. 408; 82 Stat. 5, as amended (12 U.S.C. 1730a).

11. Amend § 574.2 by revising paragraph (a)(2) and by revising the parenthetical clause in paragraph (k)(2) to read as follows:

§ 574.2 Definitions.

(a) * * *

(2) The acquisition of stock by a group of persons and/or companies acting in concert which shall be deemed to occur upon formation of such group. *Provided,* that an investment advisor shall not be deemed to acquire the voting stock of its advisee if the advisor: (i) Votes the stock only upon instruction from the beneficial owner, and (ii) does not provide the beneficial owner with advice concerning the voting of such stock.

* * * * *

(k) * * *

(2) * * * (other than a pension, profit-sharing, stockholders', voting, or business trust) * * *

* * * * *

12. Amend § 574.3 by revising paragraph (c)(2)(iv)(A) to read as follows:

§ 574.3 Acquisition of control of insured institutions.

* * * * *

(c) *Exempt transactions.* * * *

(2) * * *

(iv) * * *

(A) Has held power to vote 25 percent or more of any class of voting stock in such institution continuously since March 9, 1979; or

* * * * *

13. Amend § 574.4 by revising paragraph (d)(5) to read as follows:

§ 574.4 Control.

* * * * *

(d) * * *

(5) Persons or companies will be presumed to be acting in concert where they constitute a group under the beneficial ownership reporting rules under section 13 or the proxy rules under section 14 of the Securities Exchange Act, promulgated by the Securities and Exchange Commission.

* * * * *

14. Amend § 574.5 by revising paragraph (a)(1) to read as follows:

§ 574.5 Certifications of ownership and other reports.

(a) *Acquisition of stock.* (1) Upon the acquisition of beneficial ownership which exceeds, in the aggregate, 10 percent of any class of stock of an insured institution or additional stock above 10 percent of the stock of an insured institution occurring after December 26, 1985, an acquiror shall file in accordance with § 574.6(b)(7) of this Part a certification with the Corporation as described in this section.

* * * * *

15. Amend § 574.6 by revising paragraph (a)(3); by revising the second sentence of paragraph (e); and by revising the last sentence of paragraph (f)(2) to read as follows:

§ 574.6 Procedural requirements.

(a) * * *

(3) *H–(e)3.* This application shall be used for all applications filed under § 574.3(a): (i) By a savings and loan holding company for approval of acquisitions by a merger, consolidation, or purchase of assets of an insured or uninsured institution or a savings and loan holding company, or (ii) by any company for approval of acquisitions by a merger, consolidation, or purchase of assets of two or more insured institutions and shall be used in lieu of an application that otherwise would be required for such merger under § 546.2, § 552.13, and § 563.22 of this Chapter.

* * * * *

(e) * * * Within 20 calendar days of the date of publication (or 40 calendar days after such date if an extension is requested in writing within the initial 20-day period), anyone may file comments in favor or in protest of the application or notice, and in so doing may submit such information as he deems relevant. * * *

* * * * *

(f) *Disclosure.* * * *

(2) * * * Any such request must be substantiated in accordance with paragraph (f)(5).

* * * * *

16. Amend § 574.7 by revising paragraphs (e); (f); the introductory text of paragraph (g)(1)(ii); and paragraph (g)(1)(iii) to read as follows:

§ 574.7 Determination by the Corporation.

* * * * *

(e) *Failure to disapprove a notice.* If, upon expiration of the 60-day review period of any notice deemed to be sufficient filed pursuant to § 574.6(c), or extension thereof, the Corporation has failed to disapprove such notice, the proposed acquisition may take place; *Provided,* that it is consummated within one year and in accordance with the terms and representations in the notice and that there is no material change in circumstances prior to the acquisition.

(f) *Disapproval of a notice.* Within three business days after its decision to disapprove a notice, the Corporation or its delegate shall notify the acquiror in writing of the grounds for disapproval. If the disapproval was issued by the Principal Supervisory Agent pursuant to delegated authority, such notification shall include a statement that the acquiror may request review of the disapproval by the Corporation within 20 days of the receipt of such notification pursuant to § 574.8(a)(4). If such review is denied by the Corporation or the disapproval was issued by the Corporation, the acquiror may request an administrative hearing under paragraph (4) of the Control Act within 10 days of receipt of the notification of disapproval or notification of the Corporation's decision not to review the denial.

(g) *Presumptive disqualifiers.*

(1) * * *

(ii) Denial, or withdrawal after receipt of formal or informal notice of an intent

to deny, by the acquiror or affiliates of the acquiror, of * * *

(iii) The acquiror or affiliates of the acquiror were placed in receivership or conservatorship during the preceding 10 years, or any management official of the acquiror was a management official, director or controlling shareholder of a company or insured institution that was placed into receivership, conservatorship, or a management consignment program, or was liquidated during his tenure or control or within two years thereafter;

* * * * *

17. Amend § 574.8 by revising paragraph (a)(3)(iv) to read as follows:

§ 574.8 Delegations of authority.

(a) *Actions by the Principal Supervisory Agent.* * * *

(3) *Other actions.* * * *

(iv) A grant or denial of a request for waiver of certified financial statements for an acquiror's proprietary interests required in connection with a notice filed under § 574.3(b) of this Part: Provided, that the acquiror provides the following substitute information: (A) A statement supporting the acquiror's contention that production of such certified financial statements is unduly burdensome; (B) Tables setting forth: (i) The acquiror's percent of interest in the insured institution to be acquired, the amount of investment in the insured institution and the investment as a percentage of the acquiror's regulatory capital; and (ii) the amount of each entry as a percentage of the acquiror's total assets, regulatory capital and gross income; (C) Available unaudited financial statements for each entity for which a waiver has been requested which include at least three years of statements for each entity of operations and interim statements within 90 days of the most recently filed amendment and 2 years of statements of condition and interim statements within 90 days of the most recently filed amendments; (D) A letter from an independent accountant indicating changes that would be required to reconcile the financial statements with ones prepared on a basis that would be consistent with generally accepted accounting principles; and (E) The latest available Federal income tax returns for each entity for the immediately preceding two taxable years; and

* * * * *

By the Federal Home Loan Bank Board.

Jeff Sconyers,

Secretary.

[FR Doc. 87-6726 Filed 3-26-87; 8:45 am]

BILLING CODE 6720-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Excepted Stimulant and Depressant Compounds

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of interim rule and request for comments.

SUMMARY: This interim rule amends §§ 1308.31 and 1308.32 of the Code of Federal Regulations. Slight changes in the language of these sections have been made in order to incorporate amendments to the Controlled Substances Act of 1970 that were introduced by passage of the Dangerous Drug Diversion Control Act of 1984. These amendments change the term "excepted prescription drug" to "exempted prescription drug." In addition, the Table of Exempt Prescription Products (formerly the Table of Excepted Prescription Drugs) is amended by adding to the list those products that have been granted exempt status under the Controlled Substances Act since the last notice was published on November 29, 1982 (47 FR 53728), by removing from the list all products that have been discontinued and by rearranging the order of listing such that products will now be arranged alphabetically by name of manufacturer. This listing reflects a substantial change relative to the previous version of the Table of Exempted Prescription Products found in Part 1308.

DATES: Effective April 1, 1987. Comments must be submitted on or before April 27, 1987.

ADDRESS: Comments should be submitted in quintuplicate 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, Office of Diversion Control, Drug Enforcement Administration, 1405 I Street NW., Washington, DC 20537, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act, as amended by the Dangerous Drug Diversion Control Act of 1984, authorizes the Attorney General at 21 U.S.C. 811(g)(3)(A) to exempt from specific provisions of the Act a preparation or mixture, if that preparation or mixture contains a nonnarcotic controlled substance, is approved for prescription use, and meets certain criteria. An exemption (previously referred to as an exception) may be granted if the nonnarcotic controlled substance is combined with one or more active medicinal ingredients which are not listed in any schedule and whose presence vitiates the potential for abuse of the nonnarcotic controlled substance. Such exemptions apply only to a specific prescription product and are only granted following suitable application to Drug Enforcement Administration per 21 CFR 1308.31.

The current Table of Excepted Prescription Drugs (to be referred hereinafter as Table of Exempt Prescription Products) found in 21 CFR Part 1308, lists those products which have been granted exempt status as of November 29, 1982 (47 FR 53728). Since that time a number of applications for exemptions have been received and reviewed by the Drug Enforcement Administration. Moreover, it has been determined through direct contact with the manufacturers that a large number of prescription products previously granted exempt status are no longer being marketed. This notice adds those prescription products which have been granted exempt status since November 29, 1982 (pursuant to 21 CFR 1308.31) to the list and removes all discontinued products from the list.

It should be noted that a large number of products have been removed from the final list for one of the following reasons:

1. Information from the manufacturer indicates that the product is no longer being marketed.

2. The manufacturer could not be located by mailing address, telephone directory, listing in the 1986 edition of the American DRUG INDEX, listing in the 1986 edition of the REDBOOK, or through use of Report Number DLS-110 (Drug Manufacturer Address File) prepared by the Food and Drug Administration.

This rule also changes the terms which are used in describing both the process and the drugs involved. The statutory amendments changed the terminology from an "exception" to an "exemption." It also changed "stimulant and depressant," to "nonnarcotic." These nomenclature changes are reflected in this amendment.

This rule is being published as an interim rule with an effective date of April 1, 1987. Comments and objections will be considered, and a final rule will be published following the comment period.

The Deputy Assistant Administrator for the Office of Diversion Control hereby certifies that these matters will have no significant negative impact upon small businesses or other entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. The addition of products to the list of exempt prescription products has the effect of exempting them from certain sections of the Controlled Substances Act of 1970 and regulations.

The Office of Management and Budget has previously determined that these changes are internal agency matters which do not require formal OMB review.

List of Subjects in 21 CFR Part 1308

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

Therefore, pursuant to the authority vested in the Attorney General by 21 U.S.C. 811(g)(3)(A) as delegated to the Administrator of the Drug Enforcement Administration and redelegated to the Deputy Assistant Administrator of the Office of Diversion Control, by 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator of the Office of Diversion Control hereby amends 21 CFR Part 1308 as set forth below.

Dated: March 5, 1987.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

PART 1308—SCHEDULE OF CONTROLLED SUBSTANCES

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

Authority: 21 U.S.C. 811, 812, 871(b).

2. The centered heading prior to § 1301.31 is revised to read as follows:

Exempted Prescription Products

3. Section 1308.31 is amended by revising the section title and paragraph (a), the introductory text of paragraph (b), the first five sentences of paragraph (c), and paragraph (d) to read as follows:

§ 1308.31 Application for exemption of a nonnarcotic prescription product.

(a) Any person seeking to have any compound, mixture, or preparation containing any nonnarcotic controlled substance listed in § 1308.12(e), or in § 1308.13 (b) or (c), or in § 1308.14, or in § 1308.15, exempted from application of all or any part of the Act pursuant to section 201(g)(3)(A), of the Act (21 U.S.C. 811(g)(3)(A). may apply to the Administrator, Drug Enforcement Administration, Washington, DC 20537, for such exemption.

(b) An application for an exemption under this section shall contain the following information:

* * * * *

(c) Within a reasonable period of time after the receipt of an application for an exemption under this section, the Administrator shall notify the applicant of his acceptance or non-acceptance of the application, and if not accepted, the reason therefor. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section. If accepted for filing, the Administrator shall publish in the **Federal Register** general notice of this proposed rulemaking in granting or denying the application. Such notice shall include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule granting or denying an exemption, and, in the discretion of the Administrator, a summary of the subjects and issues involved. * * *

(d) The Administrator may any revoke any exemption granted pursuant to section 201(g)(3)(A) of the Act (21 U.S.C. 811(g)(3)(A)) by following the procedures set forth in paragraph (c) of this section for handling an application for an exemption which has been accepted for filing.

4. Section 1308.32 is amended to read as follows:

§ 1308.32 Exempted prescription products.

The following compounds, mixtures, or preparations which contain a nonnarcotic controlled substance listed is § 1308.12(e), or in § 1308.13 (b) or (c), or in § 1308.14 or in § 1308.15 listed in the Table of Exempted Prescription Products have been exempted by the Administrator from the application of sections 302 through 305, 307 through 309, 1002 through 1004 of the Act (21 U.S.C. 822–825, 827–829, and 952–954) and §§ 1301.24, 1301.31, 1301.32, and 1301.71 through 1301.76 of this chapter for administrative purposes only. Any deviation from the quantitative composition of any of the listed drugs shall require a petition for exemption in order for the product to be exempted.

Exempted Prescription Products

Explanation of Column Headings and Abbreviations

Company/Trade Name. Self explanatory.

NDC Code. Refers to the specific National Drug Code listing for the particular formulated product.

Form. Refers to the type of dosage formulation:

CA=capsule
DP=drops
EL=elixir
EC=enteric coated capsule
ET=enteric coated tablet
LQ=liquid
SS=suspension
SU=suppository
TB=tablet
WA=wafer
XC=sustained release capsule
XT=sustained release tablet

Controlled Substance (mg or mg/ml). Refers to the type and amount of controlled substance present in the mixture. If the dosage formulation is solid (CA, EC, ET, SU, TB, WA, XC, or XT), the amount shown is milligrams per dosage unit. If the dossge formulation is liquid (DP, EL, LQ, or SS), the amount shown is milligrams per milliliter.

BILLING CODE 4410-09-M

Table of Exempt Prescription Products

Company	Trade name	NDC Code	Form	Controlled Substance	(mg or mg/ml)
Adria Laboratories	Axotal	00013-1301	TB	Butalbital	50.00
Alpha Scriptics Inc	Butacet Capsules	53121-0133	CA	Butalbital	50.00
American Urologicals Inc	Butace	00539-0906	CA	Butalbital	50.00
Apotheca	Theophen	12634-0101	TB	Phenobarbital	8.00
Arco Pharmaceuticals	Arco-Lase Plus	00275-0045	TB	Phenobarbital	8.00
Arlo Interamerican	Espasmotex	11475-0835	TB	Phenobarbital	20.00
Ascher and Co	Anaspaz PB	00225-0300	TB	Phenobarbital	15.00
Ascot Pharmaceuticals	Antispasmodic Tablets	47679-0158	TB	Phenobarbital	16.20

Table of Exempt Prescription Products—Continued

Company	Trade name	NDC Code	Form	Controlled Substance	(mg or mg/ml)
Ascot Pharmaceuticals	Chlordiazepoxide Hydrochloride + Clidinium Bromide.	47679-0268	CA	Chlordiazepoxide HCl	5.00
Ayerst Laboratories	PMB-200	00046-0880	TB	Meprobamate	200.00
Ayerst Laboratories	PMB-400	00046-0881	TB	Meprobamate	400.00
Barre Drug Co	Barophen	00472-0981	EL	Phenobarbital	3.24
Barre Drug Co	Isolate Compound	00472-0929	EL	Phenobarbital	0.40
Beecham Laboratories	Hybephen	00029-2360	TB	Phenobarbital	15.00
Bioline Labs Inc	Chlordinium	00719-1208	CA	Chlordiazepoxide HCL	5.00
Blaine Co	Spaslin	00165-0029	TB	Phenobarbital	16.20
Blansett Pharm Co	Analor 300 Capsules	51674-0009	CA	Butalbital	50.00
Bock Pharmacal Co	Broncholate	00563-0277	CA	Phenobarbital	8.00
Bowman Pharmaceutical	Private Formula No 3095	00252-3095	TB	Phenobarbital Sodium	15.00
Breon Labs	Isuprel Compound	00057-0874	EL	Phenobarbital	0.40
Caldwell & Bloor Co	Hyosital White	00361-2131	TB	Phenobarbital	16.20
Carnrick Labs	Phrenilin New Formulation	00086-0050	TB	Butalbital	50.00
Chelsea Laboratories	Chlordiazepoxide with Clidinium Bromide.	46193-0948	CA	Chlordiazepoxide HCL	5.00
Columbia Drug Co	Isopap Capsules	11735-0400	CA	Butalbital	50.00
Consolidated Midland	Bellalphen	00223-0425	TB	Phenobarbital	16.20
Dorasol Laboratories	Donalixir	00471-0095	EL	Phenobarbital	3.24
Dunhall Pharmacal Inc	Triaprin	00217-2811	CA	Butalbital	50.00
Everett Laboratories Inc	Repan	00642-0162	TB	Butalbital	50.00
Forest Pharmacal Inc	Acetaminophen 325 mg/Butalbital 50 mg.	00456-0674	TB	Butalbital	50.00
Forest Pharmacal Inc	Acetaminophen 500mg/Butalbital 50mg	00456-0671	TB	Butalbital	50.00
Forest Pharmacal Inc	Bancap	00456-0546	CA	Butalbital	50.00
Forest Pharmacal Inc	Esgic Capsules	00456-0631	CA	Butalbital	50.00
Forest Pharmacal Inc	Esgic Forte Tablets	00456-0673	TB	Butalbital	50.00
Forest Pharmacal Inc	Esgic Tablets	00456-0630	TB	Butalbital	50.00
Forest Pharmacal Inc	G.B.S.	00456-0281	TB	Phenobarbital	8.00
Forest Pharmacal Inc	Soniphen	00456-0429	ET	Phenobarbital	16.00
Gen-King Products	Antispasmodic	03547-0777	TB	Phenobarbital	16.20
Geriatric Pharmacal Corp	Bilezyme Plus	00249-1112	TB	Phenobarbital	8.00
Geriatric Pharmacal Corp	Gustase Plus	00249-1121	TB	Phenobarbital	8.00
Glenlawn Laboratories	Chlordinium Sealets	00580-0084	CA	Chlordiazepoxide HCL	5.00
Halsey Drug Co	Clinoxide	00879-0501	CA	Chlordiazepoxide HCL	5.00
Halsey Drug Co	Susano	00879-0059	EL	Phenobarbital	3.24
Halsey Drug Co	Susano	00879-0058	TB	Phenobarbital	16.20
Hyrex Pharmaceutical	Panzyme	00314-0310	TB	Phenobarbital	8.10
Hyrex Pharmaceutical	Two-Dyne Revised	00314-2229	TB	Butalbital	50.00
Interstate Drug Exchange	Spastolate	00814-7088	TB	Phenobarbital	16.20
Intetlab	CON-TEN	11584-1029	CA	Butalbital	50.00
Kaiser Foundation Hosp	Belladonna Alkaloids with Phenobarbital	00179-0045	EL	Phenobarbital	3.24
Keene Pharmacal Inc	Endolar	00588-7777	CA	Butalbital	50.00
Knoll Pharmaceutical	Quadrinal Suspension	00044-4580	SS	Phenobarbital	2.40
Knoll Pharmaceutical	Quadrinal Tablets	00044-4520	TB	Phenobarbital	24.00
Kraft Pharmacal Co Inc	Digestokraft	00796-0237	TB	Butabarbital Sodium	8.00
Kremers Urban Co	Levsin with Phenobarbital Elixir	00091-4530	EL	Phenobarbital	3.00
Kremers Urban Co	Levsin with Phenobarbital Tablets	00091-3534	TB	Phenobarbital	15.00
Kremers Urban Co	Levsin-PB	00091-4536	DP	Phenobarbital	15.00
Kremers Urban Co	Levsinex with Phenobarbital	00091-3539	XC	Phenobarbital	45.00
Landry Pharmacal Inc	Febridyne Plain Capsules	05383-0001	CA	Butalbital	50.00
Lanpar Co	PB Phe-Bell	12908-7006	TB	Phenobarbital	16.20
Lasalle Laboratories	Pacaps Modified Formula	48534-0884	CA	Butalbital	50.00
Lederle Laboratories	Pathibamate-200	00005-5070	TB	Meprobamate	200.00
Lederle Laboratories	Pathibamate-400	00005-5071	TB	Meprobamate	400.00
Lemmon Pharmacal Co	Donphen	00093-0205	TB	Phenobarbital	15.00
Life Laboratories	Belladonna Alkaloids with Phenobarbital	00737-1283	EL	Phenobarbital	3.00
Mallard Inc	Anoquan Modified Formula	00166-0881	CA	Butalbital	50.00
Mallard Inc	Malatal	00166-0748	TB	Phenobarbital	16.20
Marlop Pharmacal Inc	Broncomar	12939-0128	EL	Butabarbital	1.00
Marlop Pharmacal Inc	Dolmar	12939-0812	CA	Butalbital	50.00
Marnel Pharmacal Inc	Margesic Capsules	00682-0804	CA	Butalbital	50.00
Mayrand Pharmacal Inc	B-A-C Tablets	00259-1256	TB	Butalbital	50.00
Mayrand Pharmacal Inc	Sedapap-10 Tablets	00259-1278	TB	Butalbital	50.00
Mead Johnson Pharmacal	Quibron Plus Capsules	00087-0518	CA	Butabarbital	20.00
Mead Johnson Pharmacal	Quibron Plus Elixir	00087-0511	EL	Butabarbital	1.33
Medco Supply Co	Phenobarbital & Hyoscyamine Sulfate	00764-2057	TB	Phenobarbital	16.20
Mikart Inc	Butalbital, Acetaminophen, Caffeine Capsules.	46672-0103	CA	Butalbital	50.00

Table of Exempt Prescription Products—Continued

Company	Trade name	NDC Code	Form	Controlled Substance	(mg or mg/ml)
Mikart Inc	Butalbital, Acetaminophen, and Caffeine Tablets II.	46672-0059	TB	Butalbital	50.00
Moore Drug Exchange	Antispasmodic Tablets	00839-5055	TB	Phenobarbital	16.00
Moore Drug Exchange	Theophenyllin	00839-5111	TB	Phenobarbital	8.00
Nejo Pharmaceutical	Spasmalones	00653-0002	TB	Phenobarbital	16.00
Parke-Davis & Co	Dilantin with Phenobarbital 1/2	00071-0531	CA	Phenobarbital	32.00
Parke-Davis & Co	Dilantin with Phenobarbital 1/4	00071-0375	CA	Phenobarbital	16.00
Parke-Davis & Co	Tedral SA	00071-0231	XT	Phenobarbital	25.00
Parmed Pharmaceutical	Sedapar Elixir	00349-4100	EL	Phenobarbital	3.24
Parmed Pharmaceutical	Sedapar Tablets	00349-2355	TB	Phenobarbital	16.20
Pasadena Research	Seds	00418-4072	TB	Phenobarbital	16.20
Poythress & Co Inc	Antrocol	00095-0041	CA	Phenobarbital	16.00
Poythress & Co Inc	Antrocol Elixir	00095-0042	EL	Phenobarbital	3.00
Poythress & Co Inc	Antrocol Tablets	00095-0040	TB	Phenobarbital	16.00
Poythress & Co Inc	Mudrane	00095-0050	TB	Phenobarbital	8.00
Poythress & Co Inc	Mudrane GG Elixir	00095-0053	EL	Phenobarbital	0.50
Poythress & Co Inc	Mudrane GG Tablets	00095-0051	TB	Phenobarbital	8.00
Private Formula Inc	Sangesic	00511-1627	TB	Butalbital	30.00
Redi-Med	Butalbital Compound Capsules	53506-0103	CA	Butalbital	50.00
Richlyn Laboratories	Aminophylline & Phenobarbital	00115-2156	ET	Phenobarbital	15.00
Richlyn Laboratories	Aminophylline & Phenobarbital Tablets	00115-2154	TB	Phenobarbital	15.00
Richlyn Laboratories	Bellophen	00115-2400	TB	Phenobarbital	16.20
Richlyn Laboratories	Spasmolin	00115-4652	TB	Phenobarbital	15.00
Robins A H Co Inc	Donnatal Capsules	00031-4207	CA	Phenobarbital	16.20
Robins A H Co Inc	Donnatal Elixir	00031-4221	EL	Phenobarbital	3.24
Robins A H Co Inc	Donnatal Extentabs	00031-4235	XT	Phenobarbital	48.60
Robins A H Co Inc	Donnatal No 2	00031-4264	TB	Phenobarbital	32.40
Robins A H Co Inc	Donnatal Tablets	00031-4250	TB	Phenobarbital	16.20
Robins A H Co Inc	Donnazyme	00031-4649	ET	Phenobarbital	8.10
Roche Labs	Librax	00004-0007	CA	Chlordiazepoxide HCL	5.00
Roche Labs	Menrium 10-4	00004-0025	TB	Chlordiazepoxide	10.00
Roche Labs	Menrium 5-2	00004-0023	TB	Chlordiazepoxide	5.00
Roche Labs	Menrium 5-4	00004-0024	TB	Chlordiazepoxide	5.00
Rondex Laboratories	Antispasmodic	00367-4118	TB	Phenobarbital	16.20
Rotex Pharmacal Inc	Rogesic Capsules	31190-0008	CA	Butalbital	50.00
Ruckstuhl Co	Sedarex No 3	00144-1575	TB	Phenobarbital	16.20
Rugby Laboratories	Clindex	00536-3490	CA	Chlordiazepoxide HCL	5.00
Rugby Laboratories	Hexabamate ε1	00536-3900	TB	Meprobamate	200.00
Rugby Laboratories	Hexabamate ε2	00536-3901	TB	Meprobamate	400.00
Rugby Laboratories	Hyosophen Capsules	00536-3926	CA	Phenobarbital	16.00
Rugby Laboratories	Hyosophen Tablets	00536-3920	TB	Phenobarbital	16.20
Rugby Laboratories	Theodrine Tablets	00536-4648	TB	Phenobarbital	8.00
Russ Pharmacal Inc	Analor Capsules	50474-0701	CA	Butalbital	50.00
Sandoz Pharmacal Corp	Belladenal	00078-0028	TB	Phenobarbital	50.00
Sandoz Pharmacal Corp	Belladenal-S	00078-0027	XT	Phenobarbital	50.00
Sandoz Pharmacal Corp	Bellergal-S	00078-0031	XT	Phenobarbital	40.00
Sandoz Pharmacal Corp	Cafergot P-B Suppository	00078-0035	SU	Pentobarbital	60.00
Sandoz Pharmacal Corp	Cafergot P-B Tablets	00078-0036	TB	Pentobarbital Sodium	30.00
Sandoz Pharmacal Corp	Fioricet	000088-616	CA	Butalbital	50.00
Schein Henry Inc	Antispasmodic	00364-0020	TB	Phenobarbital	16.00
Schein Henry Inc	Antispasmodic Elixir	00364-7002	EL	Phenobarbital	3.20
Schein Henry Inc	Isolate Compound Elixir	00364-7029	EL	Phenobarbital	0.40
Schein Henry Inc	T-E-P	00364-0266	TB	Phenobarbital	8.10
Shoals Pharmacal Co	Tencet Capsules	47649-0560	CA	Butalbital	50.00
Shoals Pharmacal Co	Tencet	47649-0370	TB	Butalbital	50.00
Stewart-Jackson Pharmacal	Ezol	45985-0578	CA	Butalbital	50.00
Stuart Pharmaceutical	Kinesed	00038-0220	TB	Phenobarbital	16.00
Towne Paulsen & Co	T. E. P.	00157-0980	TB	Phenobarbital	8.00
Trimen Labs	Amaphen Capsules (reformulated)	11311-0954	CA	Butalbital	50.00
Truxton C O Inc	Atropine Sulfate with Phenobarbital	00463-6035	TB	Phenobarbital	15.00
Truxton C O Inc	Ephedrine with Phenobarbital	00463-6086	TB	Phenobarbital	15.00
Truxton C O Inc	Spastemms Elixir	00463-9023	EL	Phenobarbital	3.24
Truxton C O Inc	Spastemms Tablets	00463-6181	TB	Phenobarbital	15.00
UAD Laboratories Inc	Bucet Capsules	00785-2307	CA	Butalbital	50.00
UAD Laboratories Inc	Bucet Tablets	00785-2307	TB	Butalbital	50.00
UAD Laboratories Inc	Triad	00785-2306	TB	Butalbital	50.00
UAD Laboratories Inc	Triad Capsules	00785-2305	CA	Butalbital	50.00
UDL Laboratories	Belladonna Alkaloids with Phenobarbital	51079-0168	TB	Phenobarbital	16.20
University of Iowa	Bladder Mixture Plus Phenobarbital	11326-1624	LQ	Phenobarbital	2.92
Vale Chemical Co	Alkaloids of Belladonna and Phenobarbital.	00377-0527	TB	Phenobarbital	16.20

Table of Exempt Prescription Products—Continued

Company	Trade name	NDC Code	Form	Controlled Substance	(mg or mg/ml)
Vale Chemical Co	Antispas	00377-0622	TB	Phenobarbital	16.20
Vale Chemical Co	Barbeloid (Revised) Green	00377-0365	TB	Phenobarbital	16.20
Vale Chemical Co	Barbeloid Yellow	00377-0498	TB	Phenobarbital	16.20
Vale Chemical Co	Charspast	00377-0500	TB	Phenobarbital	16.20
Vale Chemical Co	Digestokraft	00377-0460	TB	Butabarbital Sodium	8.00
Vale Chemical Co	Ephedrine & Sodium Phenobarbital	00377-0109	TB	Phenobarbital Sodium	16.20
Vale Chemical Co	Panzyme	00377-0491	TB	Phenobarbital	8.10
Vale Chemical Co	Pulsaphen	00377-0652	TB	Phenobarbital	15.00
Vale Chemical Co	Truxaphen	00377-0541	TB	Phenobarbital	16.20
Vale Chemical Co	Wescophen S-II	00377-0628	TB	Phenobarbital	30.00
Vale Chemical Co	Wesmatic Forte	00377-0426	TB	Phenobarbital	8.10
Vortech Pharmacal Co	Donna-Sed	00298-5054	EL	Phenobarbital	3.24
Vortech Pharmacal Co	Hypnaldyne	00298-1778	TB	Phenobarbital	16.20
Vortech Pharmacal Co	Isophed	00298-5680	LQ	Phenobarbital	0.40
Vortech Pharmacal Co	Phedral C. T.	00298-1173	TB	Phenobarbital	8.10
Wallace Laboratories	Barbidonna Elixir	00037-0305	EL	Phenobarbital	3.20
Wallace Laboratories	Barbidonna No 2	00037-0311	TB	Phenobarbital	32.00
Wallace Laboratories	Barbidonna Tablets	00037-0301	TB	Phenobarbital	16.00
Wallace Laboratories	Lufyllin-EPG Elixir	00037-0565	EL	Phenobarbital	1.60
Wallace Laboratories	Lufyllin-EPG Tablets	00037-0561	TB	Phenobarbital	16.00
Wallace Laboratories	Milpath-400	00037-5001	TB	Meprobamate	400.00
Wallace Laboratories	Milprem-200	00037-5501	TB	Meprobamate	200.00
Wallace Laboratories	Milprem-400	00037-5401	TB	Meprobamate	400.00
Wallace Laboratories	Miltrate-20	00037-5301	TB	Meprobamate	200.00
Wesley Pharmacal Co	Hytrophen	00917-0244	TB	Phenobarbital	16.20
Wesley Pharmacal Co	Pulsaphen Gray	00917-0113	TB	Phenobarbital	15.00
Wesley Pharmacal Co	Wescophen-S	00917-0135	TB	Phenobarbital	30.00
Wesley Pharmacal Co	Wesmatic Forte	00917-0845	TB	Phenobarbital	8.00
West-ward Inc	Belladonna Alkaloids & Phenobarbital	00143-1140	TB	Phenobarbital	16.20
West-ward Inc	Butalbital with Acetaminophen and Caffeine Tablets.	00143-1787	TB	Butalbital	50.00
West-ward Inc	Theophylline Ephedrine & Phenobarbital	00143-1695	TB	Phenobarbital	8.00
Winthrop Labs	Isuprel	00024-0874	EL	Phenobarbital	0.40
Zenith Labs Inc	Azpan	00172-3747	TB	Phenobarbital	8.00

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BILLING CODE 4410-09-D

21 CFR Part 1308

Exempt Chemical Preparations

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of interim rule and request for comments.

SUMMARY: This interim rule amends § 1308.24, of Title 21, of the Code of Federal Regulations. The below listed chemical preparations and mixtures which contain controlled substances have replaced the list of exempt chemical preparations set forth in § 1308.24(i). This action is in response to the periodic review of the exempt chemical preparation list and of applications for exemptions filed with DEA. Those preparations included in the list are exempted from the application of various provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and from certain Drug Enforcement Administration regulations.

DATES: Effective April 1, 1987. Comments must be submitted on or before April 27, 1987.

ADDRESS: Comments should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, 1405 I Street NW., Washington, DC 20537, Attn: Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, 1405 I Street, NW., Washington, DC 20537, Telephone: (202) 633-1366.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act as amended by the Dangerous Drug Diversion Control Act of 1984 authorizes the Attorney General at 21 U.S.C. 811(g)(3)(B) to exempt from specific provisions of the Act, a compound, mixture, or preparation which contains any controlled substance; which is not for administration to a human being or animal; and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

The Administrator of the Drug Enforcement Administration has received applications pursuant to § 1308.23 of Title 21 of the Code of Federal Regulations requesting approval of exempt status provided for in 21 CFR 1308.24. These applications have been received by the Deputy Assistant Administrator, Office of Diversion Control. The Deputy Assistant Administrator hereby finds that each of the following preparations and mixtures is intended for laboratory, industry, educational, or special research purposes; is not intended for general administration to man or animal; and either: (a) Contains no narcotic controlled substances and is packaged in such a form or concentration that the packaged quantity does not present any significant potential for abuse, (b) contains either a narcotic or non-narcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration, that the preparation or mixture does not present any potential for abuse, or (c) the formulation of such preparation or mixture incorporates methods of denaturing or other means so that the