

necessary to revise Regulation O in order to eliminate a requirement that is superseded by the CDR Act, and to clarify that member banks may take advantage of the recent amendment to section 22(g) of the Federal Reserve Act.

The Board, for good cause, finds that the notice and public comment procedure normally required is impractical, unnecessary, and contrary to the public interest under 5 U.S.C. 553(b)(B). The Board further finds under 5 U.S.C. 553(d)(1) that the final rule is a substantive rule that relieves a restriction on lending and therefore is making the final rule effective on April 7, 1995, without regard for the 30-day period provided for in 5 U.S.C. 553(d).

Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to publish a final regulatory flexibility analysis at the time it promulgates a final rule. One of the requirements of a final regulatory flexibility analysis, a succinct statement of the need for, and objectives of, the final rule (5 U.S.C. 604(a)(1)), is contained in the supplementary information above. For the reasons stated above concerning the need for public comment, the Board has not sought public comment on the final rule, and the Board has not considered any alternatives to the final rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. 3507, and 5 CFR 1320.130, the Board, under authority delegated by the Office of Management and Budget, has reviewed its amendments to Regulation O. The Board has determined that its final rule imposes no additional reporting or recordkeeping requirements, and that there are no relevant federal rules that duplicate, overlap, or conflict with the proposed rule. The final rule will apply to all member banks, regardless of size. The final rule should not have a negative economic impact on small institutions. Instead, the rule should relieve the regulatory burden on all member banks.

List of Subjects in 12 CFR Part 215

Credit, Federal Reserve System, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Board is amending 12 CFR Part 215, as set forth below:

PART 215—LOANS TO EXECUTIVE OFFICERS, DIRECTORS, AND PRINCIPAL SHAREHOLDERS OF MEMBER BANKS (REGULATION O)

1. The authority citation for part 215 continues to read as follows:

Authority: 12 U.S.C. 248(i), 375a(10), 375b(9) and (10), 1817(k)(3) and 1972(2)(G)(ii); Pub. L. 102-242, 105 Stat. 2236.

2. In § 215.5, paragraph (c)(2) introductory text is revised to read as follows:

§ 215.5 Additional restrictions on loans to executive officers of member banks.

* * * * *

(c) * * *

(2) In any amount to finance or refinance the purchase, construction, maintenance, or improvement of a residence of the executive officer, provided:

* * * * *

By order of the Board of Governors of the Federal Reserve System, April 3, 1995.

William W. Wiles,

Secretary of the Board.

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requirements of 21 CFR 1310.06 (a) and (b).

EFFECTIVE DATE: April 7, 1995.

FOR FURTHER INFORMATION CONTACT:

Howard McClain Jr., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537 Telephone (202) 307-7183.

SUPPLEMENTARY INFORMATION:

On October 11, 1994, the Acting Administrator of the DEA published an interim rule (59 FR 51364) which clarified what records shall be adequate to satisfy recordkeeping requirements for listed chemical transactions under provisions of the Controlled Substances Act (CSA) as amended by the Chemical Diversion and Trafficking Act of 1988 (CDTA) and the Domestic Chemical Diversion Control Act of 1993 (DCDCA). Specifically, this interim rule clarified that for prescription drug products, prescription and hospital records kept in the normal course of medical treatment are adequate to meet the recordkeeping requirements for each record required under 21 CFR 1310.03. However, the interim notice stated that reports as specified in 21 CFR 1310.05 and notification requirements as set forth in 21 CFR 1313 must still be satisfied for these products. Interested parties had until November 10, 1994 to submit comments and objections.

In response to the October 11, 1994 interim rule, one comment was submitted by Abbott Laboratories. In this comment Abbott requested that records for the distribution of prescription ephedrine injectable products, which are kept in the normal course of business, be considered adequate to satisfy the recordkeeping requirements, just as prescription and hospital records kept in the normal course of medical treatment shall be considered adequate. Abbott further stated that normal business records contain (1) the name and address of both parties to the transaction; (2) the date of the regulated transaction; (3) the name and quantity of the prescription drug product; (4) the method of transfer; and (5) an Abbott customer identification number.

Upon review of Abbott's comment, DEA has determined that no further amendment to the regulations are required. Existing provisions of 21 CFR 1310.06 (which detail the sufficiency of records kept in the normal course of business) are broad enough to enable businesses to meet the requirements pertaining to injectable ephedrine products without any new burden. Therefore, the interim rule (59 FR

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[DEA No. 122F]

RIN 1117-AA25

Contents of Records and Reports

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: The interim rule published by the Deputy Administrator of the Drug Enforcement Administration (DEA) to clarify what records shall be adequate to satisfy recordkeeping requirements for Listed Chemical transactions under provisions of the Controlled Substances Act (CSA) as amended by the Chemical Diversion and Trafficking Act of 1988 (CDTA) and the Domestic Chemical Diversion Control Act of 1993 (DCDCA) is adopted without change. Specifically, the amendment clarifies that for prescription drug products, prescription and hospital records shall be adequate to satisfy recordkeeping requirements. In addition, this final rule clarifies that for the distribution of these products to hospitals, pharmacies and other entities, normal business records shall be considered adequate if they meet the

51364) is herein finalized without change.

The contents of records required for regulated transactions are stated in 21 CFR 1310.06. Specifically, 21 CFR 1310.06(a)(5) provides that each record shall include the type of identification used by the purchaser and any unique number on that identification. It is the responsibility of the regulated person who engages in a regulated transaction to identify the other party to the transaction and verify the existence and apparent validity of a business entity ordering a listed chemical in compliance with 21 CFR 1310.07. If the assignment of a company customer identification number is based upon meeting all requirements as specified in 21 CFR 1310.07, and this customer identification number can be cross-referenced with the type of identification used to verify the existence and apparent validity of the purchaser and any unique number on that identification, then a customer identification number will be deemed adequate to meet the requirements of 21 CFR 1310.06(a)(5).

Further, 21 CFR 1310.06(b) states that normal business records shall be considered adequate if they contain the information listed in 21 CFR 1310.06(a) and are readily retrievable from other business records of the regulated person. Thus, if these records are readily retrievable and meet all the requirements of 21 CFR 1310.06(a) then these records shall be deemed adequate. However, it is the responsibility of each regulated person to ensure that all requirements of 21 CFR 1310.06 are adequately met if relying on normal business records to satisfy the recordkeeping requirements of 21 CFR 1310.03.

The products in question are prescription products which are already subject to strict Federal and state controls. This final rule modifies 21 CFR 1310.06(b) to reflect that for purposes of this section, prescription and hospital records kept in the normal course of medical treatment shall be adequate to meet recordkeeping requirements.

This rule has been drafted and reviewed in accordance with Executive Order 12866, Section 1(b), Principles of Regulation. The Deputy Administrator has determined that this rule is not a significant regulatory action under Executive Order 12866 Section 3(f), Regulatory Planning and Review. This action allows relief from regulatory requirements by permitting the use of normal business records for these prescription products rather than requiring the creation of separate

records of transactions. Accordingly, this rule has not been reviewed by the Office of Management and Budget.

The Deputy Administrator in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1310

Drug traffic control, Reporting and recordkeeping requirements.

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

Accordingly, the interim rule amending 21 CFR part 1310 which was published at 59 FR 51364 on October 11, 1994, is adopted as a final rule without change.

Dated: March 20, 1995.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[IN-121; Amendment 94-7]

Indiana Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Indiana regulatory program (hereinafter referred to as the "Indiana program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Indiana proposed revisions to the Indiana Surface Coal Mining rules pertaining to the backfilling and grading of surface coal mining and reclamation operations. The amendment is intended to provide additional safeguards and clarify ambiguities.

EFFECTIVE DATE: April 7, 1995.

FOR FURTHER INFORMATION CONTACT:

Roger W. Calhoun, Director, Indianapolis Field Office, OSM, Minton-Capehart Federal Building, Room 301, Indianapolis, Indiana 46204. Telephone: (317) 232-1547.

SUPPLEMENTARY INFORMATION:

- I. Background on the Indiana Program.
- II. Submission of the Proposed Amendment.
- III. Director's Findings.
- IV. Summary and Disposition of Comments.
- V. Director's Decision.
- VI. Procedural Determinations.

I. Background on the Indiana Program

On July 29, 1982, the Secretary of the Interior conditionally approved the Indiana program. Background information on the Indiana program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the July 29, 1982, **Federal Register** (47 FR 32071). Subsequent actions concerning conditions of approval and program amendments can be found at 30 CFR 914.10, 914.15, and 914.16.

II. Submission of the Proposed Amendment

By letter dated January 31, 1995, (Administrative Record No. IND-1420) Indiana submitted a proposed amendment to its program pursuant to SMCRA at its own initiative. Indiana proposed to revise 310 IAC 12-5-54.1—Surface Mining: Backfilling and Grading, Timing Limitations.

OSM announced receipt of the proposed amendment in the February 17, 1995, **Federal Register** (60 FR 9313), and in the same document opened the public comment period and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on March 20, 1995.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment.

Revisions not specifically discussed below concern nonsubstantive wording changes, or revised cross-references and paragraph notations to reflect organizational changes resulting from this amendment.

310 IAC 12-5-54.1—Surface Mining: Backfilling and Grading, Timing Limitations

Indiana is revising subsection (a) to make several nonsubstantive wording changes. At subsection (a)(1), Indiana is requiring that backfilling and grading in