FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone: (202) 307–7297.

SUPPLEMENTARY INFORMATION: The Controlled Substances Act of 1970 (CSA) sets forth a system to control and prevent the diversion of controlled substances. Title 21, Code of Federal Regulations (21 CFR), Parts 1300 to End contains the specific regulatory requirements to implement the CSA, including the registration, recordkeeping, security, reporting and quota provisions. Title 21 CFR 1301.22(a) describes the eleven activities that require registration with DEA. Under this section, manufacturing and research are designated as independent activities for which separate registrations are required. However, 21 CFR 1301.22(b) describes specific coincident activities for which separate registrations are not required. Specifically, 21 CFR 1301.22(b)(5) states that a person registered or authorized to conduct research with controlled substances listed in Schedules II through V shall be authorized, among other things, to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application, and to distribute such substances to other persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances.

The present DEA policy permits the manufacture of small amounts of bulk material under a researcher registration if: (1) the quantities are set forth in, and consistent with, the statement filed with the application for registration,; and (2) if the purpose, as set forth in the statement filed with the application, is to develop synthesis procedures or other research not related to dosage form development.

This policy is necessary to preserve the closed system of distribution, as well as protect the integrity of the attendant quota, security, recordkeeping and reporting requirements of the system. DEA is obligated to enforce the distinctions among those independent activities set forth in 21 CFR 1301.22(a). Manufacturers are held to more stringent requirements than researchers because of the greater threat of diversion associated with manufacturing.

It has come to the attention of DEA that certain registrants are manufacturing bulk material under a researcher registration for the purpose of: (1) performing dosage form development (to include associated regulatory requirements such as production of batches as mandated by the Food and Drug Administration (FDA); or (2) distributing such material to other research registrants for furtherance of dosage form development and associated requirements. In addition, several dosage form manufacturers have procured large quantities of Schedule II controlled substances under researcher registrations for use in product development. Activities of this type are not consistent with the mandate of the CSA to maintain a closed regulatory system to prevent diversion. In order to ensure that all registrants understand the meaning and requirements of 21 CFR 1301.22 and to ensure adequate safeguards against diversion, DEA is issuing this clarification of the permissible scope of manufacturing under a researcher registration.

For the purposes of 21 CFR part 1301, the following dosage form development activities are not considered research and must be conducted under a manufacturer registration: (a) activities for the purpose of satisfying regulatory requirements such as FDA submissions or good manufacturing practice; (b) activities associated with establishing the manufacturing processes and procedures, including, but not limited to, production of material used for pilot, scale-up and reformulation studies, as well as the studies themselves; and (c) all activities associated with such development including, but not be limited to, bioavailability, formulation, stability, an validation studies. While these activities may be considered research under FDA requirements, 21 CFR part 1301 must be read within the context of the CSA and its attendant requirements concerning quotas, recordkeeping, security and reporting. DEA does not consider such dosage form development to be a coincident research activity as contemplated by 21 CFR 1301.22(b); the production of material for such activities is manufacturing. The exemption for separate registrations for certain coincident activities is intended to facilitate research by allowing for the limited manufacture of controlled substances for those activities related directly to the research set forth in the statement filed with application for researcher registration. However, once the manufacture of controlled substances for research moves beyond the scope of the research and becomes product development, as described above, those manufacturing activities are not longer considered to be coincident activities. Any person seeking to manufacture controlled substances for such purposes must meet the primary requirements for registration as a manufacturer as set forth in 21 U.S.C. 823.

Requiring registration as a manufacturer for product development activities will present no additional obstacles, due to DEA's Final Rule, published on June 20, 1995 (60 FR 32099, Registration of Manufacturers and Importers of Controlled Substances), to amend the regulations to eliminate the requirement of an administrative hearing on objections, raised by third-party manufacturers, to the registration of certain bulk manufacturers of controlled substances. As noted in the Final Rule, DEA is aware that some manufacturers have attempted to use the hearing process to obstruct or delay action on new applications for registration as a bulk manufacturer. This may have contributed to the practice of conducting product development activities under researcher registrations to avoid such delays. The amendment of the hearing requirements removes any such justification for resorting to such practices.

DEA cannot predict when an individual's activities may shift from a researcher to a manufacturer. Therefore, it is imperative that a person who is conducting research, whose activities move from bench type to scale up and development, be aware and alert to the requirements of 21 CFR 1301.22. For any questions or guidance in this area, DEA should be contacted for a specific clarification.

Dated: October 24, 1995.

Gene R. Haislip,

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

[FR Doc. 95–26948 Filed 10–30–95; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8611]

RIN 1545–AS40

Conduit Arrangement Regulations; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to final regulations (TD

8611), which were published in the Federal Register for Friday, August 11, 1995 (60 FR 40997). The final regulations relate to conduit financing arrangements issued under the authority granted by section 7701(l).

EFFECTIVE DATE: September 11, 1995.

FOR FURTHER INFORMATION CONTACT: Elissa J. Shendalman of the Office of the Associate Chief Counsel (International), (202) 622–3870 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections are under sections 871, 881, 1441, 1442, and 7701(l) of the Internal Revenue Code.

Need for Correction

As published, TD 8611 contains typographical errors that are in need of correction.

Correction of Publication

Accordingly, the publication of the final regulations which is the subject of FR Doc. 95–19446, are corrected as follows:

§ 1.881–3 [Corrected]

1. On page 41013, column 3, § 1.881–3, paragraph (e), paragraph (i) of *Example 25.*, line 1, the figure ''10,000,000'' is corrected to read ''5,000,000''.

2. On page 41013, column 3, § 1.881–3, paragraph (e), paragraph (i) of *Example 25.*, line 5, the figure ''5,000,000'' is corrected to read ''10,000,000''.

3. On page 41013, column 3, § 1.881–3, paragraph (e), paragraph (iii) of *Example 25.*, the first sentence ''Pursuant to paragraph (d)(1)(i) of this section, the amount subject to recharacterization is a fraction the numerator of which is the average principal amount advanced from FS to DS and denominator of which is the average principal amount advanced from FP to FS.'' is corrected to read ''Pursuant to paragraph (d)(1)(i) of this section, the amount subject to recharacterization is a fraction the numerator of which is the lowest aggregate principal amount advanced and the denominator of which is the principal amount advanced from FS to DS.''.

§ 1.1441–7 [Corrected]

4. On page 41015, column 2, § 1.1441–7, paragraph (d)(2)(ii), paragraph (i) of *Example 4.*, the language ''size. BK2 considers BK1 to enter into a loan'' is corrected to read ''size. BK2 considers asking BK1 to enter into a loan''.

Cynthia E. Grigsby,

Chief, Regulations Unit Assistant Chief Counsel (Corporate).

[FR Doc. 95–26786 Filed 10–30–95; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 162–1–7250a; FRL–5321–1]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on revisions to the California State Implementation Plan. The revisions concern rules from the South Coast Air Quality Management District (SCAQMD). This approval action will incorporate these rules into the federally approved SIP. The intended effect of approving these rules is to regulate emissions of volatile organic compounds (VOCs) in accordance with the requirements of the Clean Air Act, as amended in 1990 (CAA or the Act). In addition, the final action on these rules serves as a final determination that the deficiencies in previous versions have been corrected and that on the effective date of this action, any sanctions or Federal Implementation Plan (FIP) obligations are permanently stopped. The revised rules control VOC emissions from graphic arts and the coating of wood products. Thus, EPA is finalizing the approval of these revisions into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards and plan requirements for nonattainment areas.

DATES: This action is effective on January 2, 1996 unless adverse or critical comments are received by November 30, 1995. If the effective date is delayed, a timely notice will be published in the Federal Register.

ADDRESSES: Copies of the rule revisions and EPA's evaluation report for each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule revisions are available for inspection at the following locations:

Rulemaking Section (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Environmental Protection Agency, Air Docket (6102), 401 ''M'' Street, SW., Washington, DC 20460.

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 ''L'' Street, Sacramento, CA 92123–1095.

South Coast Air Quality Management District, 21865 E. Copley Drive, Diamond Bar, CA 91765–4182.

FOR FURTHER INFORMATION CONTACT: Daniel A. Meer, Chief Rulemaking Section (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1185.

SUPPLEMENTARY INFORMATION:

Applicability

The rules being approved into the California SIP include: SCAQMD Rules 1130, Graphic Arts, and 1136, Wood Products Coating. These rules were submitted by the California Air Resources Board (CARB) to EPA on October 16, 1995.

Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act, as amended in 1977 (1977 Act or pre-amended Act), that included the South Coast Air Basin. 43 FR 8964, 40 CFR 81.305. On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2)(H) of the 1977 Act, that the above districts' portions of the California SIP were inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, the Clean Air Act Amendments of 1990 were enacted. Pub. L. 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401–7671q. In amended section 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for states to submit corrections of those deficiencies.

Section 182(a)(2)(A) applies to areas designated as nonattainment prior to enactment of the amendments and classified as marginal or above as of the date of enactment. It requires such areas to adopt and correct RACT rules pursuant to pre-amended section 172(b)