

If DEA's inspections or audits reveal that Respondent still does not maintain its records of receipt in a readily retrievable and current manner, the Deputy Administrator will remove the stay and revoke Respondent's DEA Certificate of Registration. However, if the inspections reveal that Respondent is now maintaining its records of receipt in compliance with DEA regulations, then the Deputy Administrator will withdraw this final order and the final order published on July 16, 1996, will permit Respondent to retain its registration, and will renew the registration.

Also to avoid further confusion within the controlled substance industry and to address the concerns set forth in this final order, the Deputy Administrator directs that DEA's Office of Diversion Control finalize the regulations relating to disposers of controlled substances and relating to the freight forwarding of controlled substances.

Accordingly, the Deputy Administrator of the Drug Enforcement Administration, pursuant to the authority vested in him by 21 U.S.C. 823 and 824 and 28 CFR 0.100(b) and 0.104, hereby orders that the stay of revocation of DEA Certificate of Registration RR0166113, issued to RX Returns, Inc., that is set forth in the final order dated July 5, 1996 and found at 61 FR 37,801 (July 16, 1996), be, and it hereby is, continued for one year from the effective date of this final order, subject to the above described conditions. This final order is effective October 29, 1999.

Dated September 20, 1999.

**Donnie R. Marshall,**  
Deputy Administrator.

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### Manufacturer of Controlled Substances; Notice of Registration

By Notice dated February 23, 1999, and published in the **Federal Register** on March 5, 1999 (64 FR 10725), Sigma Aldrich Research Biochemicals, Inc., Attn: Richard Milius, 1-3 Strathmore Road, Natick, Massachusetts 01760 made application to the Drug Enforcement Administration (DEA) by letter to be registered as a bulk manufacturer of fentanyl (9801).

A registered bulk manufacturer of fentanyl filed written comments and an objection in response to the notice of application. Review of the APA's

definitions of license and licensing reveals that the granting or denial of a manufacturer's registration is a licensing action, not a rulemaking. Courts have frequently distinguished between agency licensing actions and rulemaking proceedings. See, e.g. *Gateway Transp. Co. v. United States*, 173 F. Supp. 822, 828 (D.C. Wis. 1959); *Underwater Exotics, Ltd. v. Secretary of the Interior*, 1994 U.S. Dist. LEXIS 2262 (1994). Courts have interpreted agency action relating to licensing as not falling within the APA's rulemaking provisions.

The objector argues that Sigma Aldrich Research Biochemicals, Inc. cannot prove its registration as a bulk manufacturer of fentanyl is in the public interest, that Sigma Aldrich Research Biochemicals, Inc.'s registration is not required to produce an adequate and uninterrupted supply of fentanyl, that there is sufficient competition with the present bulk manufacturers.

The arguments of the objector were considered, however, DEA has reviewed the firm's safeguards to prevent that theft and diversion of fentanyl and found that the firm has met the regulatory requirements and public interest factors of the Controlled Substances Act.

Sigma Aldrich Research Biochemicals, Inc. has been and is currently registered with DEA as a manufacturer of other Schedule II controlled substances. Sigma Aldrich Research Biochemicals, Inc.'s application is based on the firm's request to add fentanyl to its existing registration as a bulk manufacturer. The firm has been investigated by DEA on a regular basis to determine if the firm maintains effective controls against diversion and if its continued registration is consistent with the public interest. These investigations have included, in part, inspection and testing of the firm's physical security, audits of the firm's records, verification of compliance with state and local law and a review of the firm's background and history. These investigations have found Sigma Aldrich Research Biochemicals, Inc. to be in compliance with the Controlled Substances Act (C.S.A.) and its implementing regulations in recent years.

Under Title 21, Code of Federal Regulations, § 1301.43(b), DEA is not required to limit the number of manufacturers solely because a smaller number is capable of producing an adequate supply provided effective controls against diversion are maintained. DEA has determined that effective controls against diversion will be maintained by Sigma Aldrich Research Biochemicals, Inc.

After reviewing all the evidence, DEA has determined, pursuant to 21 U.S.C. 823(a), that it is consistent with the public interest to grant Sigma Aldrich Research Biochemicals, Inc.'s application to manufacture fentanyl at this time. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator, Office of Diversion Control, hereby orders that the application submitted by the above firm for registration as a bulk manufacturer of the basic class of controlled substance listed above is granted.

Dated: September 16, 1999.

**John H. King,**

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

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## DEPARTMENT OF LABOR

### Employment and Training Administration

#### Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA-W) issued during the period of August and September, 1999.

In order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number of proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increased or imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sale or production.

#### Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3)