Drug	Schedule
Noroxymorphone (9668)	II

The firm plans to manufacture small quantities of the listed controlled substances for reference standards.

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the above application.

Any such comments or objections may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, D.C. 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than (60 days from publication).

Dated: July 3, 1996.

Gene R. Haislip,

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

[FR Doc. 96–18022 Filed 7–15–96; 8:45 am]

BILLING CODE 4410–01–M

Manufacturer of Controlled Substances; Notice of Registration

By notice dated September 5, 1995, and published in the Federal Register on September 13, 1995, (60 FR 47591), Mallinckrodt Chemical, Inc., Mallinckrodt & Second Streets, St. Louis, Missouri 63147, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of methylphenidate (1724) a basic class of controlled substance listed in Schedule II. Also, by Notice dated March 27, 1996, and published in the Federal Register on April 4, 1996 (61 FR 15120), Mallinckrodt Chemical, Inc., Mallinckrodt & Second Streets, St. Louis, Missouri 63147, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Tetrahydrocannabinols (7370)	I
Methylphenidate (1724)	II
Cocaine (9041)	II
Codeine (9050)	II
Diprenorphine (9058)	II
Etorphine Hydrocholoride (9059)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Diphenoxylate (9170)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II
Meperidine (9230)	II
Methadone (9250)	II
Methadone-intermediate (9254)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273)	II
Morphine (9300)	II
Thebaine (9333)	II
Opium extracts (9610)	II
Opium fluid extract (9620)	II
Opium tincture (9630)	II
Opium powdered (9639)	II
Opium granulated (9640)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II
Noroxymorphone (9668)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

On July 20, 1995, and January 31, 1996, Mallinckrodt Chemicals, Inc. (Mallinckrodt) filed applications with the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of methylphenidate. DEA published notices of these applications in the Federal Register on September 13, 1995, and April 4, 1996, respectively. One registered manufacturer of bulk methylphenidate filed comments in response to these notices. The commentor argues that DEA failed to comply with the Administrative Procedure Act (APA) and further alleges that Mallinckrodt's registration would be contrary to the public interest pursuant to 21 U.S.C. 823(a). The commentor requested a hearing on the 1995 application and urged DEA to deny the 1996 application, or, at a minimum, issue an order to show cause proposing to deny the application.

With respect to the first notice, published September 13, 1995, the commentor alleges that it is entitled to a hearing on Mallinckrodt's application since the regulation terminating the third party hearing right (21 C.F.R. 1301.43(a)) did not take effect until the end of the day on July 20, 1995. The commentor argues that, since Mallinckrodt's application was filed during the day on July 20, 1995, the commentor is entitled to ask for and obtain a hearing. The commentor maintains that if DEA were to consider the application under the new regulation, it would be in violation of Section 553(d) of the Administrative Procedure Act (APA) which dictates that there must be thirty days between publication of a rule and its effective date.

DEA is not persuaded by the commentor's argument that the new regulation could not have become effective until the *end* of the day on July 20, 1995, i.e. after the filing of Mallinckrodt's application during the day of July 20, 1995. In any event, the commentor's contention regarding the effective date of the new regulation is, at this point, moot. Mallinckrodt did not manufacture any methylphenidate pursuant to its application published on July 20, 1995. The commentor thus was not prejudiced by the lack of a hearing. Convening a hearing regarding Mallinckrodt's July 1995 application would serve no purpose.

Furthermore, Mallinckrodt has since filed a new application, published in April 1996. There is no question that Mallinckrodt's 1996 application was filed after the effective date of the new regulation. As a result, the commentor enjoys no right to request or receive a hearing regarding Mallinckrodt's 1996 application.

The commentor next asserts that the 60 day comment period was an insufficient amount of time for the commentor to gather information regarding Mallinckrodt' application. However, in amending the regulation, DEA did not intend to encourage third parties to become, in essence, independent investigators. DEA's intent in amending 21 C.F.R. 1301.43(a) was to allow third parties to provide information already known to the third parties regarding an applicant. It is DEA's position, therefore, that 60 days are sufficient to permit third parties to share information of which they are aware regarding an applicant.

The commentor argues that the notices of Mallinckrodt's applications failed to provide third parties, including the commentor, with an opportunity for meaningful, informed comment. The commentor concludes that DEA has violated the rulemaking provisions of Section 553(b) of the APA. Contrary to the commentor's contention, for the reasons set forth below, DEA's registration of bulk manufacturers does not constitute a ''rulemaking'' proceeding. Nor did DEA voluntarily adopt notice and comment rulemaking procedures when it amended 21 C.F.R. 1301.43(a).

First, the commentor has ignored the definitions set forth in the APA and, in so doing, confuses notice and comment rulemaking with agency licensing proceedings. The commentor insists that DEA proceedings to grant or deny an application for registration as a bulk manufacturer are rulemakings. The APA, however, defines ''rule making'' to mean an ''agency process for formulating, amending, or repealing a rule.'' 5 U.S.C. 551(5). The APA defines a ''rule'' as:

> the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing.

5 U.S.C. 551(4).

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.

In *Underwater Exotics,* the United States District Court for the District of Columbia drew the distinction between an agency placing conditions on a license and an agency creating a rule. In that case, the plaintiff was licensed by the Fish and Wildlife Service (Service) to import and export certain aquatic species. When the Service imposed certain conditions on the plaintiff's license, plaintiff sued, arguing, *inter alia,* that the Service failed to comply with the APA's rulemaking requirements.

The court looked to the APA's definitions of ''licensing'' and ''rule'' and concluded that ''the Service's imposition of these conditions on a license did not violate the APA, because the Service's actions did not involve the creation of a rule.'' 1994 U.S. Dist. LEXIS 2262, *26. The court further stated that:

> the Service's imposition of conditions on the plaintiff's import/export license clearly fall within the definitions of ''license'' and ''licensing,'' * * * this agency action is not a ''rule making.'' Absent specific statutory direction otherwise, a court should not force an agency to employ a certain procedural format * * *.

Id.

Since the registration of bulk manufacturers is not a ''rule,'' DEA is not required to follow traditional notice and comment rulemaking procedures when granting or denying applications for such registration. In fact, the D.C. Circuit clearly supported this analysis in a 1980 decision in which the court stated that ''agency action that clearly falls outside the definition of 'rule' is also freed from rulemaking procedures.'' *Batterton* v. *Marshall,* 648 F. 2d 694, 701 n. 25 (D.C. Cir. 1980).

Furthermore, the commentor's contention that DEA voluntarily adopted notice and comment rulemaking with its amendment of 21 C.F.R. 1301.43(a) is not supported by either the notice of proposed rulemaking or the final rule. In fact, while the final rule does invite written comments form current manufacturers and applicants, nowhere in the final rule does DEA state, implicitly or explicitly, that it intended to follow notice and comment rulemaking procedures when acting upon a bulk manufacturer's application. DEA simply stated in the final rule that it would take into account such written comments when deciding whether to grant a particular registration or issue an order to show cause proposing to deny an application.

If DEA determines, based on information provided to it in written comments and its own investigation, that the registration of an applicant would not be in the public interest, an order to show cause will be issued. The decision of whether to issue an order to show cause is solely within DEA's discretion. If the applicant requests a hearing, the ensuing adjudicatory proceedings will comply with the APA. DEA's decision to address applications via individual adjudication, and not by notice and comment rulemaking, is within its discretion and in conformity with both the APA and the Controlled Substances Act (CSA). Courts have held that agencies have this discretion to determine whether to proceed by rulemaking or individual adjudication. *See PBW Stock Exchange* v. *Securities and Exchange Commission,* 485 F. 2d 718, 731 (3d Cir. 1973) *cert denied* 94 S. Ct. 1992 (1974).

Finally, the commentor's citation to *Rodway* v. *USDA,* 514 F. 2d 809 (D.C. Cir. 1975) and *Heron* v. *Heckler,* 576 F. Supp. 218 (N.D. Cal. 1983) is inappropriate. In those cases, as the commentor itself acknowledges, the agencies in question had either promulgated a regulation or adopted a policy statement specifically espousing the APA's notice and comment requirements. DEA has done neither.

DEA's action upon a bulk manufacturer's application is not a rulemaking action. DEA is therefore not required to follow notice and comment rulemaking when considering these applications. Neither the APA nor the CSA requires DEA to follow notice and comment rulemaking when acting upon bulk manufacturer applications. While DEA invites comments from competitors and applicants, such invitation does not translate into an implicit adoption of notice and comment rulemaking.

The commentor makes several allegations regarding its claim that Mallinckrodt's registration would not be consistent with the public interest pursuant to 21 U.S.C. 823(a). First, with respect to 21 U.S.C. 823(a) (1), (2), and (5), the commentor alleges that Mallinckrodt lacks effective controls to prevent diversion, noting past instances of violations of the CSA and its implementing regulations relating to recordkeeping and security. The commentor also draws attention to violations of the Food Drug and Cosmetic Act. The commentor further notes that Mallinckrodt has been cited by both federal and state authorities for violations of environmental laws and regulations.

With respect to Mallinckrodt's compliance with the CSA and its implementing regulations, Mallinckrodt is currently registered with DEA as a bulk manufacturer of other Schedule II controlled substances. It is true that DEA issued letters of admonition to Mallinckrodt in 1990 and 1991. The problems identified in these letters, however, were not significant enough to prompt DEA to seek revocation of Mallinckrodt's registration. Further, Mallinckrodt acted expeditiously to correct those problems.

Since the issuance of the letters of admonition, DEA has investigated Mallinckrodt to ensure that the company's continued registration is consistent with the public interest. These investigations have included inspection and testing of the company's physical security systems, audits of the company's records, verification of the company's compliance with state and local laws, and a review of the company's background and history. The results of these investigations have led DEA to conclude that Mallinckrodt is in compliance with the CSA and that its continued registration is consistent with the public interest.

The commentor also notes Mallinckrodt's violation of Food and Drug Administration (FDA) regulations. DEA has verified that Mallinckrodt's registration with the FDA is current and is confident that the nature of the FDA violations does not warrant the initiation of proceedings to deny Mallinckrodt's applications.

In addition, the commentor points out that Mallinckrodt has been cited by the United States Environmental Protection Agency and the State of North Carolina for violations of environmental regulations. In the absence of evidence

that these violations relate to the manufacture, distribution, or dispensing of controlled substances, DEA declines to consider them for purposes of determining whether Mallinckrodt's registration would be in the public interest.

The commentor further alleges that there currently exists an adequate and uninterrupted supply of methylphenidate under adequately competitive conditions. Consequently, the commentor claims that registration of an additional manufacturer could lead to an increased threat of diversion. In support of its position, the commentor points to a background paper published by DEA in which DEA voiced concerns about the diversion of methylphenidate. As the commentor itself noted, however, DEA's paper concluded that this diversion results from illegal sales by health care professionals, overprescribing by physicians, and illegal sales by end-users. As the commentor acknowledges, there is little evidence of diversion occurring at the bulk manufacturer level.

The commentor contends that, since currently registered manufacturers of methylphenidate produce an adequate and uninterrupted supply of the drug to meet the legitimate needs of the United States, registration of another manufacturer is not needed. The commentor argues that ''there is no evidence that the registration of Mallinckrodt * * * will have a beneficial effect upon competition.'' The CSA, however, does not demand that such a finding be made before DEA can register a bulk manufacturer. Furthermore, pursuant to 21 CFR 1301.43(b), DEA is not:

> required to limit the number of manufacturers in any basic class to a number less than that consistent with maintenance of effective controls against diversion solely because a smaller number is capable of producing an adequate and uninterrupted supply.

As is discussed above, DEA is confident that registration of Mallinckrodt will not impede DEA's statutory obligation to guard against the diversion of controlled substances.

With respect to 21 U.S.C. 823(a)(3), the commentor questions whether Mallinckrodt will promote technical advances in the art of manufacturing methylphenidate and the development of new substances. Mallinckrodt has been registered with DEA since 1971. In the past 25 years, Mallinckrodt has demonstrated its technical and manufacturing expertise with respect to other controlled substances. Based on this history, DEA is confident that Mallinckrodt will continue this practice if registered to manufacture methylphenidate.

Regarding 21 U.S.C. 823(a)(4), the commentor admits that it is unaware of any prior convictions of Mallinckrodt. DEA has verified that Mallinckrodt and its principals have not been convicted under Federal or state laws relating to the manufacture, distribution or dispensing of controlled substances.

Finally, under 21 U.S.C. 823(a)(6), the commentor again argues that Mallinckrodt's alleged lack of compliance with various FDA regulations indicates that its registration as a bulk manufacturer of methylphenidate would be inconsistent with the public interest. For the reasons set forth above, DEA does not feel that the nature of the noted violations warrants issuing an order to show cause to seek to deny Mallinckrodt's applications.

After reviewing all the evidence, including the comments filed, DEA has determined, pursuant to 21 U.S.C. 823(a), that registration of Mallinckrodt as a bulk manufacturer of methylphenidate is consistent with the public interest at this time. Therefore, pursuant to 21 U.S.C. 823 and 28 CFR 0.100 and 0.104, the Deputy Assistant Administrator hereby orders that the 1996 application submitted by Mallinckrodt for registration as a bulk manufacturer of the listed controlled substances, including methylphenidate, is granted. The Deputy Assistant Administrator declines to take action on Mallinckrodt's 1995 application since, given that Mallinckrodt did not manufacture methylphenidate pursuant to its 1995 application and has since submitted an application for 1996, it is unnecessary to do so.

Dated: July 10, 1996.

Gene R. Haislip,

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

[FR Doc. 96–18024 Filed 7–15–96; 8:45 am]

BILLING CODE 4410–09–M

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated February 26, 1996, and published in the Federal Register on March 4, 1996, (61 FR 8303), MD Pharmaceutical, Inc., 3501 West Garry Avenue, Santa Ana, California 92704, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Methylphenidate (1724)	II
Diphenoxylate (9170)	II

No comments or objections have been received. DEA has considered the factors in 21 U.S.C. 823(a) and determined that the registration of MD Pharmaceutical, Inc. to manufacture the listed controlled substances is consistent with the public interest at this time. Therefore, pursuant to 21 U.S.C. 823 and 28 C.F.R. 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 classes of controlled substances listed above is granted.

Dated: July 3, 1996.

Gene R. Haislip,

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

[FR Doc. 96–18023 Filed 7–15–96; 8:45 am]

BILLING CODE 4410–09–M

[Docket No. 94–77]

RX Returns, Inc.; Revocation of Registration

On August 15, 1994, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration (DEA), issued an Order to Show Cause to RX Returns, Inc., (Respondent) of Palm, Pennsylvania, notifying it of an opportunity to show cause as to why DEA should not revoke its DEA Certificate of Registration, RR0166113, and deny any pending applications for renewal of its registration as a distributor (disposer), under 21 U.S.C. 823(e), as being inconsistent with the public interest. Specifically, the Order to Show Cause alleged in relevant part that:

(1) On March 19, 1992, the Respondent entered into a Memorandum of Understanding (MOU) with DEA, where, in exchange for its receiving a DEA registration as a distributor (disposer) of controlled substances, it agreed to comply with security, inventory, and recordkeeping requirements of a DEA registrant;

(2) In July 1992, a DEA investigation of the Respondent revealed numerous recordkeeping and security violations. As a result, on September 24, 1992, DEA conducted an informal hearing in which the Respondent was given an opportunity to reply to allegations regarding violations of 17 recordkeeping and security requirements.