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.