will not be enforceable against a transition or democratically elected government in Cuba under section 302(d).

(l) Claimants bringing an action under Title III will be required to pay a uniform filing fee, to be established by the Judicial Conference of the United States, pursuant to section 302(i).

(m) Section 302(a)(6) provides that no court of the United States shall decline, based upon the act of state doctrine, to make a determination on the merits in an action brought under Title III.

(n) Section 305 provides that actions under section 302 may not be brought more than two years after the trafficking giving rise to the action has ceased to occur.

4. Proof of Ownership of a Claim to Confiscated Property

(a) Section 303(a) provides that certification of a claim by the FCSC is conclusive proof of ownership. In all other cases, the court has the discretion to appoint a special master, including the FCSC, to make determinations of the amount and ownership of the claim. Determinations made by administrative agencies or courts of a foreign government or international organization shall not be conclusive unless made pursuant to binding international arbitration to which the United States or the claimant submitted the claim.

(b) Section 303(b) amends the International Claims Settlement Act of 1949 by authorizing a U.S. district court to refer to the FCSC factual questions under Title III involving the amount and ownership by a U.S. national of a claim to confiscated property in Cuba.

5. Consistency With International Claims Practice

(a) Section 303(c) emphasizes that nothing in the LIBERTAD Act shall be construed to require or otherwise authorize the claims of Cuban nationals who became U.S. citizens after their property was confiscated to be included in a future negotiation and espousal of U.S. claims with a friendly government in Cuba when diplomatic relations are restored. Section 303(c) also states that the LIBERTAD Act shall not be construed as superseding, amending, or otherwise altering certifications that have been made under the FCSC's Cuba Claims Program.

(b) Section 304 amends the International Claims Settlement Act of 1949 to state that no person other than a certified claimant shall have a claim to, participate in, or otherwise have an interest in the compensation proceeds paid to a U.S. national by virtue of a certified claim.

6. Presidential Suspension Authority

(a) Section 306(a) provides that, subject to the President's suspension authority, Title III takes effect on August 1, 1996.

(b) Section 306(b) provides the President with the authority to suspend the effective date of Title III beyond August 1, 1996, for up to six months, and for additional extensions up to six months, upon a determination and report to the appropriate congressional committees that a suspension is necessary to the national interests of the United States and will expedite a transition to democracy in Cuba. An initial determination and report must be submitted to the appropriate congressional committees at least 15 days before August 1, 1996. Additional suspensions or extensions are subject to the same reporting and determination requirements.

(c) Section 306(c) provides the President with the authority to suspend the right to bring an action under Title III after its effective date for up to six months, and for additional extensions up to six months, upon a determination and report that a suspension is necessary to the national interests of the United States and will expedite a transition to democracy in Cuba. Section 306(c) also emphasizes that after the effective date no persons may acquire a property interest in any potential or pending Title III action, nor shall pending actions commenced before the date of suspension be affected by a suspension.

(d) Section 306(d) provides that the President may rescind any suspension made under section 306(b) or section 306(c) upon reporting to the appropriate congressional committees that doing so will expedite a transition to democracy in Cuba.

Dated: May 11, 1996.

Janet Reno,

Attorney General.

[FR Doc. 96–12407 Filed 5–16–96; 8:45 am]

BILLING CODE 4410–01–M

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By notice dated August 14, 1995, and published in the Federal Register on August 22, 1995 (60 FR 43613), Ganes Chemicals, Inc., Industrial Park Road, Pennsville, New Jersey 08070, made application to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of methylphenidate.

A registered manufacturer of bulk methylphenidate filed a comment alleging that DEA's notice of application, published in the Federal Register, did not comply with notice and comment rulemaking requirements of the Administrative Procedure Act (APA). In addition, the commentor stated that Ganes' registration would be contrary to the public interest under 21 U.S.C. 823(a).

The commentor maintains that DEA ''has deprived [the commentor] and other registered manufacturers and applicants of the opportunity to offer fully-informed comments on Ganes' application.'' In support of its position, the commentor submits that ''registration of bulk manufacturers of schedule I–II controlled substances is subject to notice and comment rulemaking.'' For the reasons provided below, this conclusion is an incorrect interpretation of the APA. First, the commentor ignores the basic definitions set forth in the APA and, in so doing, confuses notice and comment rulemaking with agency licensing proceedings. The commentor argues that DEA proceedings to grant or deny an application for registration as a bulk manufacturer are rulemakings. However, the clear language of the definition of a ''rule'' exposes the error of this analysis. The APA 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 therefore 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 [1] and licensing [2] reveals that the granting or denial of a manufacturer's application for registration is a licensing action, not a rulemaking. Courts have

[1] Section 551(8) of the APA defines license as ''the whole or a part of an agency permit, certificate, approval, *registration*, charter, membership, statutory exemption or other form of permission.'' (emphasis added).

[2] Licensing is defined as ''agency process respecting the grant, renewal, denial, revocation, suspension, annulment, withdrawal, limitation, amendment, modification, or conditioning of a license.'' 5 U.S.C. 551(9).

frequently distinguished between agency licensing actions and rulemaking proceedings. *See, e.g., Gateway Transportation 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). Since courts have interpreted agency action relating to licensing as not falling within the APA's rulemaking provisions, it is probably not an oversight that the commentor has not cited any cases in which an agency action on a license was required to comport with § 553 of the APA.

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 agency creation of a rule. In that case, the Fish and Wildlife Service (Service) imposed certain conditions on the plaintiff's import/export license; the 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 explained 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, in a case cited by the commentor, clearly supported this analysis in a 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).

In a final rule which amended 21 CFR § 1301.43(a), effective July 20, 1995, DEA eliminated the right of current bulk manufacturers or applicants to request a hearing on an application to bulk manufacture a Schedule I or II controlled substance. In the regulation as amended, however, DEA continued to invite comments and objections from such manufacturers or applicants on a pending application. (60 FR 32099 (June 20, 1995)). The commentor claims that DEA voluntarily adopted the APA's notice and comment procedures when it changed the third party hearing regulation in the final rule of June 20, 1995. This contention, however, is not supported by either the notice of proposed rulemaking (59 FR 3055) or the final rule. In fact, while the final rule does invite written comments from current manufacturers and applicants, nowhere in this 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 whether to issue an Order to Show Cause proposing to deny an application.

The commentor contends that ''[w]ithout access to * * * Ganes' application, any reports of DEA inspections of Ganes, or DEA's assessment of how it might apply the statutory public interest test, it is impossible for [the commentor] and other registered manufacturers to offer fully-informed comments on Ganes' fitness for registration.'' Nowhere in the final rule was it contemplated that DEA would turn over information in its files in order for others to determine whether to object or not. DEA is well aware of what it has in its own files and will supplement that information with any comments filed in rendering a decision whether or not to grant an application. In determining whether an applicant meets the public interest standard, DEA is perfectly capable of analyzing its own investigative reports. Therefore, it is not necessary for DEA to turn over information it has gathered on a particular applicant to another registered manufacturer.

Moreover, under 21 U.S.C. 824(a), only the Attorney General has the discretion to decide whether or not to file an Order to Show Cause. The rule amending 21 CFR 1301.43 did not and, indeed, could not, authorize a third party to exercise such discretion in light of the clear statutory mandate to place such decisions exclusively with the Attorney General.

If DEA determines, based upon its own investigation and upon information provided to it through written comments, that the registration of an applicant would not be in the public interest, an Order to Show Cause will be issued. 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.

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.

The commentor also submitted that the sixty day comment period was inadequate because that commentor needed more time to obtain and assess documents from DEA and the U.S. Department of Health and Human Services, Food and Drug Administration. The regulation, as amended June 20, 1995, contemplated that DEA would receive information from qualified third parties that is already available and known to such parties. As explained above, the intent of the regulation never was to have other bulk manufacturers or applicants become an independent investigative branch. Under these circumstances, the sixty-day comment period is adequate.

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 other bulk manufacturers and applicants, such invitation does not translate into an implicit adoption of notice and comment rulemaking. Consequently, the sixty day comment in which to file comments is reasonable and adequate.

On February 14, 1996, the Commentor filed a belated, additional comment. This comment maintained that the dictum set forth in *MD Pharmaceutical, Inc.* v. *Drug Enforcement Administration,* No. 95–1267 (D.C. Cir. January 2, 1996) required DEA to set forth the reasons why DEA intends to register Ganes under certain factors set forth in 21 U.S.C. 823(a). Whether or not the Commentor's interpretation is correct or not, DEA will adequately address the commentor's objections and

set forth the reasons why DEA believes Ganes' application should be granted under the factors pursuant to 21 U.S.C. 823(a) as set forth below.

In stating that Ganes Chemicals, Inc.'s application to manufacture methylphenidate would be contrary to the public interest under 21 U.S.C. 823(a), the commentor argues that Ganes would lack effective controls against diversion of methylphenidate; that Ganes' past experience in the manufacture of controlled substances and experience in the establishment of effective control against diversion were questionable; that there is currently an adequate and uninterrupted supply of methylphenidate under adequately competitive conditions; and that there were other relevant factors to indicate that Ganes' registration would be contrary to the public health and safety.

In support of the contentions that Ganes lacks effective controls to prevent diversion and that Ganes' past experience in this regard was questionable, the commentor states that as a result of an Order to Show Cause issued by DEA and a Civil Complaint filed in the United States District Court for the District of New Jersey charging Ganes with various security and record-keeping violations and with manufacturing controlled substances in excess of quotas, Ganes entered into a Consent Agreement in December 1980, agreeing to withdraw its application to bulk manufacture methaqualone and not reapply until 1984 and pay a $25,000 fine.

Ganes' application is based on the firm's request to add methylphenidate to its existing registration as a bulk manufacturer. Ganes has been and is currently registered with DEA as a bulk manufacturer of other Schedule II controlled substances. Both the Order to Show Cause and the civil complaint occurred over fifteen years ago. The firm has been investigated by DEA on a regular basis since that time 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. The investigations have found Ganes to be in compliance with the CSA and its implementing regulations.

The commentor argues that there is an adequate and uninterrupted supply of methylphenidate under adequately competitive conditions. In support of this argument, the commentor asserts that the present bulk manufacturers are adequate for this purpose, that quota restrictions have been eased sufficiently since 1988, and that the commentor sells methylphenidate in dosage form to itself and other distributors.

Under Title 21, CFR 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 Ganes.

The commentor, in support of its argument that Ganes' registration would be contrary to the public health and safety, cites Ganes' manufacture of the List I chemicals, ephedrine and pseudoephedrine. The commentor states that DEA has reported that ephedrine and pseudoephedrine are used in the clandestine manufacture of methamphetamine and methcathinone and that companies such as Ganes may be the source of these chemicals.

With respect to Ganes' manufacture of ephedrine and pseudoephedrine, there is no evidence of any violations of the Chemical Diversion and Trafficking Act (CDTA) and the Domestic Chemical Diversion Control Act (DCDCA).

Another factor which the commentor claims is relevant is that the Food and Drug Administration (FDA) has made various inspections of Ganes' two production centers between 1980 and 1994, and noted various problems with record keeping, manufacturing practices and product-complaint procedures. The commentor states that some of these findings pertain to controlled substances.

The FDA violations are based on the practices of another federal agency within another department of government operating under the authority of distinctly different statutes. Moreover, DEA has verified with FDA that Ganes' drug registration under the Federal Food, Drug and Cosmetic Act is current, that the nature of the indicated (or noted) FDA citations against Ganes and the FDA actions to ensure compliance do not warrant a finding that Ganes' compliance with Federal laws is so lacking or inadequate as to warrant denial under the CSA.

It is within DEA's sole discretion to decide whether or not to file an Order to Show Cause after reviewing all of the evidence, including the comments and objections provided to DEA under 21 CFR 1301.43(a). After reviewing all the evidence, including the comment filed, DEA has determined, pursuant to 21 U.S.C. 823(a), that it is consistent with the public interest to grant Ganes' application to manufacture methylphenidate 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 classes of controlled substances listed above is granted.

Dated: May 13, 1996.

Gene R. Haislip,

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 May, 1996.

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 or 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 increases of 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 sales or production.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA–W–32,177; EMI Co., Erie, PA