criteria will be developed ''* * * with the purpose of promoting the highest level of water use efficiency reasonable achievable by project contractors using best available cost-effective technology and best management practices.''

The MP Criteria states that all parties (districts) that contract with Reclamation for water supplies (municipal and industrial contracts over 2,000 irrigable acre-feet and agricultural contracts over 2,000 irrigable acres) will prepare water management plans which will be evaluated by Reclamation based on the following required information detailed in the steps listed below to develop, implement, monitor, and update their water management plans. The steps are:

1. Describe the district.
2. Inventory water resources available to the District.
3. Best Management Practices (BMP's) for Agricultural Contractors.
4. BMP's for Urban Contractors.
5. Exemption Process.

The MP contractors listed below have developed water management plans which Reclamation has evaluated and preliminarily determined to meet the requirements of the Criteria. The districts are:

- Hills Valley Irrigation District,
- Ivanhoe Irrigation District,
- Lower Tule River Irrigation District,
- Pixley Irrigation District,
- Porterville Irrigation District,
- Saucelito Irrigation District,
- Southern San Joaquin Municipal Utilities District,
- Stone Corral Irrigation District,
- Terra Bella Irrigation District.
- Public comment on Reclamation's preliminary (i.e., draft) determinations is invited at this time. Copies of the plans listed above will be available for review at Reclamation's MP Regional office and MP's Area Office. If you wish to review a copy of the plans, please contact Ms. Billingsley to find the office nearest you.

Dated: October 8, 1998.

Robert F. Stackhouse,

Regional Resources Manager Mid-Pacific Region.

[FR Doc. 98–27914 Filed 10–16–98; 8:45 am]

BILLING CODE 4310–94–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Notice of Registration

By Notice dated June 30, 1998, and published in the **Federal Register** on July 9, 1998, (63 FR 37137), Damocles10, 3529 Lincoln Highway, Thorndale, Pennsylvania 19372, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Heroin (9200)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Phenmetrazine (1631)	II
Hydromorphone (9150	II
Morphine (9300)	II

The firm plans to manufacture the listed controlled substances for the purpose of deuterium labeled internal standards for distribution to analytical laboratories.

No comments or objections have been received. DEA has considered the factors in Title 21, United States Code, Section 823(a) and determined that the registration of Damocles10 to manufacture the listed controlled substances is consistent with the public interest at this time. DEA has investigated Damocles10 on a regular basis 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. 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: October 6, 1998.

John H. King,

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

[FR Doc. 98–27971 Filed 10–16–98; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 95–47]

Roxane Laboratories, Inc.; Intent To Allow the Importation of a Schedule II Substance, Grant of Registration To Import a Schedule II Substance

I. Introduction

A. History

On February 15, 1995, Roxane Laboratories, Inc. (hereinafter Roxane) applied to the Drug Enforcement Administration (DEA) for registration as an importer of the Schedule II substance cocaine pursuant to 21 U.S.C. 958(i)(1993). On June 8, 1995, DEA published notice of this application in the **Federal Register**, 60 FR 30,320 (1995). This notice advised that any manufacturer holding or applying for registration as a manufacturer of this basic class of controlled substance could file written comments or objections to the application and could also file a written request for a hearing on the application in accordance with 21 CFR 1301.43.[1]

In response to this publication, Stepan and Noramco submitted written comments, and by letter dated July 7, 1995, Mallinckrodt Chemical, Inc. (hereinafter Mallinckrodt) file a timely request for a hearing. Following prehearing procedures, a hearing was held in Arlington, Virginia, on February 5 through 9 and March 4 through 7, 1996, before Chief Administrative Law Judge Mary Ellen Bittner. Roxane, Mallinckrodt and DEA all participated in the hearing and were represented by counsel. At the hearing, all parties called witnesses to testify and introduced documentary evidence. After the hearing, all parties filed proposed findings of fact and conclusions of law and briefs. Roxane filed a rejoinder brief. On September 23, 1997, Judge Bittner issued her Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision, recommending that the Acting Deputy Administrator issue a regulation permitting the importation of bulk cocaine by hydrochloride and that he grant Roxane's application for registration as an importer of bulk cocaine hydrochloride. On November 7,

[1] Subsequent to the hearing in this matter, DEA's Federal regulation citations were changed by final order. 65 FR 13,938 (March 24, 1997). Regulatory citations in the record and in the Administrative Law Judge's Opinion and Recommended Ruling, Findings of Fact, Conclusion of Law and Decision use the previous numbering system. This decision uses the current numbering system.

1997, Mallinckrodt and Romaine filed exceptions to the findings of fact and conclusions of law of the Administrative Law Judge.

On December 10, 1997, the Administrative Law Judge certified and transmitted the record to the Acting Deputy Administrator of DEA. The record included the Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision of the Administrative Law Judge, the findings of fact and conclusions of law proposed by all parties, the exceptions filed by the parties, motions filed by all counsel, all the exhibits and affidavits, and all of the transcripts of the hearing sessions.

B. Regulatory Context

In accordance with the DEA Statement of Policy and Interpretation on registration of importers, 40 FR 43,745 (1975), the Acting Deputy Administrator will not grant Roxane's application unless Roxane establishes that the requirements of 21 U.S.C. 958(a) and 823(a) and of 21 CFR 1301.34(b)–(f) are met. Also, because DEA will not maintain a ''contingency reserve'' of registrants, Roxane must establish that cocaine may be imported pursuant to 21 U.S.C. 952(a)(2)(B), as a prerequisite to its registration as an importer of cocaine hydrochloride. As a result, this proceeding is inherently a combined rulemaking on whether the Schedule II controlled substance cocaine hydrochoride may lawfully be imported into the United States pursuant to 21 U.S.C. 952, and an adjudication on Roxane's application for registration as an importer of cocaine pursuant to 21 U.S.C. 958(a).

C. The Record

In the adjudication, the Acting Deputy Administrator will issue his final order based on the record made before the Administrative Law Judge. However, there is not requirement that the decision regarding the issuance of a regulation to allow the importation of a cocaine hydrochloride be made on the record. Hence, in the rulemaking the Acting Deputy Administrator may consider information or submission in addition to those contained in the record created by the Administrative Law Judge. After the hearing, Mallinckrodt and Roxane filed separate motions to reopen the record and introduce additional evidence, which the Administrative Law Judge denied. The Acting Deputy Administrator had reviewed the record, and makes the following decision regarding these motions.

In the adjudication, the Acting Deputy Administrator has the authority to request that the Administrative Law Judge reopen the record and admit evidence that was not introduced in the hearing. However, the standard for doing so is that the party seeking to introduce such evidence must show that the new evidence was previously unavailable and is material and relevant to the matters in dispute. *Immigration and Naturalization Service* v. *Abudu,* 485 U.S. 94 (1988); *Robert M. Golden, M.D.,* 61 FR 24,808, 24,812 (1996). The only information sought to be introduced after the hearing that is relevant to the issues to be resolved in the adjudication aspect of this case is the information regarding whether Germany has used seized materials in manufacturing cocaine hydrochloride that Roxane sought to introduce by its motion dated May 29, 1996. However, the issue raised by Mallinckrodt in these proceedings is limited to whether the bulk cocaine hydrochloride that Roxane will import into the United States is manufactured from seized materials. Therefore, the Acting Deputy Administrator finds that evidence regarding Germany's use of seized materials in general is irrelevant to these proceedings. The Acting Deputy Administrator also agrees with the Administrative Law Judge's finding that this information could have been obtained by Roxane earlier in the proceedings if Roxane had exercised due diligence. For these reasons, the Acting Deputy Administrator finds that Roxane has failed to make the requisite showing for reopening the record.

The general purpose of the rulemaking procedure is to gather information, and when making a rule the agency wants to have access to as much information as possible. As a result, the informal rulemaking proceeding does not end with the same degree of finality as does a formal adjudication. Charles H. Koch, Jr., *Administrative Law and Practice,* § 4.84 (1985). The agency may want to consider information obtained after the close of the comment period, and the courts have generally supported this practice. *See Sierra Club* v. *Costle,* 657 F.2d 198 (D.C. Cir. 1981); *Hoffman-La Roche, Inc.* v. *Kleindienst,* 478 F.2d 1, 13–15 (3d Cir. 1973). Nonetheless, at some point the agency must make a decision, and it is free to ignore comments that were filed late. *Personal Watercraft Industry Ass'n, et al.* v. *Dept. of Commerce,* 48 F.3d 540, 542–43 (D.C. Cir. 1995). In this case, the most logical point to close the rulemaking record is December 10, 1997, when the record was transmitted from the Administrative Law Judge to the Acting Deputy Administrator for a final decision. By this date, interested persons wishing to make comments on whether the importation of cocaine hydrochloride should be permitted pursuant to 21 U.S.C. 952(a)(2)(B) had more than two years to submit comments to this agency. Furthermore, it was at this point in the proceeding that the Acting Deputy Administrator began his final review of the record.

The only information received prior to December 10, 1997 that is relevant to the rulemaking aspects of this case and was excluded by the Administrative Law Judge is the information Mallinckrodt sought to introduce regarding its cocaine sales and pricing for fiscal years 1996 and 1997, the rebuttal evidence offered by Roxane, and the comments submitted by Noramco, Inc. For the foregoing reasons, the Acting Deputy Administrator has included this information in the record on which he relied in making a final determination on the rulemaking aspect of this case. The comments of Mallinckrodt and Roxane that were submitted to the Acting Deputy Administrator subsequent to December 10, 1997 were not included in the rulemaking record.

D. The Protective Order

On December 1, 1995, the Administrative Law Judge issued a Protective Order which limited access to any information introduced in the hearing that was designated ''Confidential and Protected''. Both Mallinckrodt and Roxane filed Motions to Add to the Confidential and Protected Designations in this matter after the Administrative Law Judge certified and transmitted the record to the Acting Deputy Administrator. All parties to the proceeding were provided with copies of these motions and had ample time to make their objections known. However, no party has objected to Mallinckrodt's and Roxane's motions, and the subject matter of those items sought to be designated as Confidential and Protected is within the scope of original Protective Order issued February 5, 1996. Therefore, Mallinckrodt's and Roxane's filings, both dated December 29, 1997, are granted. However, as the parties were informed in the original Protective Order, this agency is bound by the provisions of the Freedom of Information Act, 5 U.S.C. 552(b), and pursuant to the Protective Order, ''the DEA will afford the producing party sufficient advance notice prior to any such disclosure to allow that party to pursue appropriate remedies to preserve the information's protected status.''

The Acting Deputy Administrator has carefully reviewed the entire record in this matter, as defined above, and hereby issues this final rule as prescribed by 21 CFR 1316.67, and final order as prescribed by § 1301.46, based upon the following findings and conclusions. The Acting Deputy Administrator adopts the Findings of Fact, Conclusions of Law, and Recommended Ruling of the Administrative Law judge, with specifically noted exceptions, and his adoption is in no manner diminished by any recitation of facts, issues and conclusions herein, or of any failure to mention a matter of fact or law. Further, all exceptions to the Administrative Law Judge's decision have been considered by the Acting Deputy Administrator.

II. Rulemaking

A. Threshold Issues

As stated above, Roxane cannot be registered as an importer of cocaine hydrochloride pursuant to 21 U.S.C. 958(a) and 823(a) and 21 CFR 1301.34(b)–(f) unless the Acting Deputy Administrator finds that cocaine hydrochloride may be imported pursuant to 21 U.S.C. 952(a)(2)(B). Because Roxane is the proponent of the issuance of such a rule, it must establish by a preponderance of the credible evidence that such a rule can be issued.

Section 952(a) of the Controlled Substances Act prohibits the importation of cocaine hydrochloride into the United States, except in three narrow circumstances. Section 952(a)(2) allows for the importation of:

> [S]uch amount of any controlled substance in schedule I or II * * * that the Attorney General finds to be necessary to provide for the medical, scientific, or other legitimate needs of the United States— (A) during an emergency in which domestic supplies of such substance or drug are found by the Attorney General to be inadequate, (B) In any case in which the Attorney General finds that competition among domestic manufacturers of the controlled substance is inadequate and will not be rendered adequate by the registration of additional manufacturers under section 823 of this title, or (C) in any case in which the Attorney General finds that such controlled substance is in limited quantities exclusively for scientific, analytical, or research uses.

Roxane proposes that competition in the domestic cocaine hydrochloride manufacturing market is inadequate and therefore, the Acting Deputy Administrator should issue a rule allowing importation of cocaine hydrochloride pursuant to 21 U.S.C. 952(a)(2)(B).

Mallinckrodt argues that the Acting Deputy Administrator cannot promulgate such a rule because importation of cocaine hydrochloride is not necessary, with the meaning of the statute, as Mallinckrodt is able to meet all the legitimate needs of the domestic market. Mallinckrodt also argues that Roxane has not carried its burden of establishing that there is inadequate competition in the domestic market or that the registration of additional manufacturers would not render competition adequate.

1. Relevance of Domestic Manufacturers Ability To Supply the Market

Whether a finding that domestic manufacturers are unable to supply the legitimate market is a condition precedent to important pursuant 21 U.S.C. 952(a)(2) is a threshold issue, as it is undisputed that Mallinckrodt is currently able to manufacture a sufficient amount of bulk cocaine hydrochloride to meet the legitimate needs of the United States.

An extensive reading of the legislative history reveals that the protection of the American consumer was of primary importance to Congress, and such protection was its intent in drafting the inadequate competition exception to the general ban on importation of Schedule I and II controlled substances. The Acting Deputy Administrator finds that it would be inconsistent with Congress' intent to interpret the statue as Mallinckrodt suggests, as such an interpretation would prevent the agency from protecting the American consumer when a domestic manufacturer is able to meet the legitimate needs of the United States, even where an egregious state of inadequate competition results in a tremendous cost to the consumer.

The Acting Deputy Administrator also agrees with the Administrative Law Judge that Mallinckrodt's interpretation of section 952(a)(2) would render the inadequate competition exception superfluous because a finding that domestic needs were not being met would constitute an emergency, in which case importation would be permitted pursuant to 21 U.S.C. 952(a)(2)(A). The Acting Deputy Administrator also finds Mallinckrodt's reliance upon a Memorandum of Law issued by former Administrative Law Judge Francis L. Young to be misplaced. As Administrative Law Judge Bittner suggests, this Memorandum of Law was never incorporated into a final order, and therefore, is not precedent. Further, the Acting Deputy Administrator does not agree with Administrative Law Judge Young's analysis regarding the necessity of finding that domestic needs were not being met before importation could be permitted pursuant to 21 U.S.C. 952(a)(2)(B). Administrative Law Judge Young apparently believed that Congress did not intend the Controlled Substances Act to be a substitute for the antitrust laws. However, as previously stated, the legislative history as a whole indicates that it was the intent of Congress to combine the Attorney General's antitrust responsibilities with those designed to control the illicit drug market, for the protection of the consumer who has a therapeutic need for these substance.

2. Treaty Obligations

Mallinckrodt also argues that as long as it is able to supply the domestic market, issuing a regulation which allows the importation of cocaine hydrochloride would be a violation of this country's obligations under the Multilateral Single Convention on Narcotic Drugs of 1961. However, the Acting Deputy Administrator finds that as long as the amounts imported and manufactured are controlled through the import permit procedures and the quota system to avoid an excess supply of cocaine hydrochloride that would require warehousing, this country's obligations under the treaty will be satisfied.

For the foregoing reasons, the Acting Deputy Administrator agrees with the finding of the Administrative Law Judge that there is no requirement in the statute that the agency may not permit importation of cocaine hydrochloride because Mallinckrodt is able to supply the licit domestic market. Rather, if the Acting Deputy Administrator finds that importation is permitted pursuant to 21 U.S.C. 952(a)(2)(B), the specific amounts to be imported will be determined through the import permit procedures of 21 CFR 1312.11–.19.

3. Level of Production at Which To Analyze Competition

Federal regulations specify the factors that must be considered when making the determination whether competition is inadequate within the meaning of the statute. See 21 CFR 1301.34(d), (e) and (f). However, before turning to those factors, it must be determined at which level of production competition is to be analyzed. Mallinckrodt asserts that any analysis of the degree of competition among domestic manufacturers of cocaine must include dosage form manufacturers, such as Roxane. Roxane, on the other hand, argues that competition must be reviewed only at the level of production at which it is alleged to be inadequate. In this case, it is alleged that competition is inadequate at the level of where bulk cocaine hydrochloride is manufactured.

The Acting Deputy Administrator finds unpersuasive the testimony of Walter Vandaele, Ph.D., an economic expert, that competition should be analyzed at the level of dosage form manufacturers because it is at that level where cocaine competes with other products. Dosage form manufacturers do not manufacture cocaine; they purchase it in bulk from Mallinckrodt, package it in a variety of forms, and market it to the consumer. Dr. Vandaele offers no further explanation of this statement, and it seems disingenuous as the statute requires that competition among manufacturers, not between products, be analyzed. The Acting Deputy Administrator does find persuasive the testimony of another economic expert, Keith Leffler, Ph.D., that inadequate competition at the bulk cocaine stage of production affects all levels of production. At a minimum, it is clear that the pricing effects of inadequate competition at the bulk cocaine level will affect the minimum price that the dosage form manufacturers can charge for their cocaine products. As a result, no degree of competition among the dosage form manufacturers will protect the consumer from the pricing effects of inadequate competition among the bulk cocaine manufacturers. Therefore, the Acting Deputy Administrator finds that the appropriate level of production at which to measure the adequacy of competition is that level where bulk cocaine is manufactured.

B. Adequacy of Competition

1. Scope of Market in Which Competition To Be Analyzed

In turning to the factors of 21 U.S.C. 1301.34 that are to be considered in analyzing competition, it seems most appropriate to begin with 21 U.S.C. 1304.34(e). This section provides that in determining the scope of the market in which the degree of competition is to be analyzed, the Acting Deputy Administrator must consider substitute products which are reasonably interchangeable with cocaine in terms of price, quality and use. There is a considerable amount of disagreement between the parties as to whether any such substitutes exist, and a significant amount of the evidence and testimony was directed toward this issue.

It is undisputed in the record that no single drug produced by any manufacturer can duplicate the vasoconstrictive and anesthetic effects of cocaine. All parties agree that cocaine is pharmacologically unique.

Nonetheless, Mallinckrodt asserts that there are four products which are substitutes for cocaine, within the meaning of 21 U.S.C. 1304.34(e). These products, according to Mallinckrodt, are the following combinations of drugs: lidocaine-adrenaline-tetracaine; oxymetazoline-lidocaine; xylometazoline-lidocaine; and lidocaine-phenylephrine. However, no pharmaceutical company or manufacturer of pharmaceutical drugs manufactures a combination of these drugs in a single product. Rather, it is up to the consumer to formulate a solution, using two or more of these drugs, to emulate the effects of cocaine. In fact, the record reveals that at one hospital, the pharmacy refuses to mix such formulas for different practitioners in the operating room because it is time-consuming and it increases the hospital's liability. For these reasons, the Acting Deputy Administrator finds that none of the combinations of drugs that have been promoted as substitutes for cocaine are ''products'' within the meaning of 21 U.S.C. 1304.34(e).

However, assuming that these drug combination are products for purposes of the regulation, it is also clear from the record that Mallinckrodt's assertion that these combinations have the same effects as cocaine is only correct to a limited extent. The medical literature submitted by Mallinckrodt does support its assertion that the consumer is looking to replace cocaine. Nonetheless, this literature also demonstrates that although these alternatives may be replacing cocaine with respect to some procedures, the evidence does not support a finding that there are alternatives to cocaine when performing all procedures with a local anesthetic and vasoconstrictor. Most notably, there is no evidence that the medical profession views these alternatives to cocaine as viable options when performing procedures that cause deep periosteal pain or are relatively long in duration.

In this regard, the Acting Deputy Administrator find particularly persuasive Mallinckrodt's exhibit that reports the results of an intensive program aimed at reducing the use of cocaine solution at the Medical Center Hospital of Vermont. *See Mallinckrodt Exhibit 105.* Mallinckrodt and its experts refer to the results of this effort often, asserting that the resulting sixty six percent reduction in the use of cocaine is strong evidence that a lidocaine-phenylephrine solution is a substitute for cocaine. However, the article detailing the results of this study reports that despite this intense effort to eliminate the use of cocaine, the otolaryngology department only used the lidocaine-phenylephrine solutions for examinations, minor procedures and minor trauma, and reserved cocaine for major trauma and surgical procedures. Therefore, while this study indicates that some combinations of drugs that consumer have formulated have replaced cocaine in some applications, it also further supports the finding that the medical profession does not consider these combinations to be substitutes for cocaine in all procedures where the use of a topical anesthetic and vasoconstrictor is indicated.

A significant amount of the evidence and argument also related to whether or not any of the drug combinations were economic substitutes for cocaine. The Administrative Law Judge found this issue particularly important, as she found that although there are alternatives to cocaine, these alternatives are not substitute products within the meaning of the statute because they are not economic substitutes for cocaine, and more importantly, because there is no quantitative evidence that these alternatives have impacted on the market for cocaine. Mallinckrodt contends that this finding of the Administrative Law Judge is erroneous, as it limits the term ''substitute'' in a way that is not supported by the plain language of the regulation or the relevant case law. Mallinckrodt argues that the most important factor in determining whether or not two products are substitutes for each other is whether the products are used interchangeably by the consumers.

The Acting Deputy Administrator finds that language of 21 CFR § 1304.34(e) is not so limiting as to require that products be economic substitutes that impact on the relevant market to be considered substitutes, but evidence of this nature is relevant. The statute clearly states that products are substitutes if they are reasonably interchangeable in terms of price, quality and use. If products are interchangeable in this manner, it logically follows that temporary fluctuations in the price, quality or availability of one product will temporarily impact on the market for the other product.

However, the Acting Deputy Administrator finds that the combinations of various drugs that are being promoted as substitutes for cocaine are not being used interchangeably with cocaine by the consumer. The medical evidence in the record indicates that cocaine is being permanently replaced by certain combinations of drugs with respect to certain procedures. There is no shifting back and forth between products. Mallinckrodt's own medical experts

testified that there has been a ''conversion'' to these alternative drug combinations, and they could conceive of no reason why they would return to using cocaine.

The word ''interchangeable'' is a term of art in the field of antitrust law. Where products are interchangeable, consumers shift back and forth between them based upon a variety of economic and quality based factors. The Acting Deputy Administrator agrees with Roxane that it is exactly this type of dynamic shifting between products that indicates that they are reasonably interchangeable. Furthermore, the case law that the parties rely on, as well as the Department of Justice and FTC Merger Guidelines (1992), contemplate this type of shifting of demand in response to changes in the competitiveness of any given product in the relevant market. The Acting Deputy Administrator finds that the record establishes that there is no such shifting of demand between cocaine and the drug combinations promoted as being substitutes for it.

For the foregoing reasons, the Acting Deputy Administrator finds that none of the drug combinations offered as alternatives to cocaine are ''products'' within the meaning of 21 U.S.C. 1304.34(e). However, even if these drug combinations are ''products'' within the meaning of the regulation, they are not reasonably interchangeable with cocaine in terms of price, quality or use, and thus do not quality as ''substitutes''. Having found that the relevant market for the purposes of 21 CFR 1304.34(e) is limited to cocaine, the Acting Deputy Administrator will confine has analysis of competition to the manufacturers of cocaine hydrochloride in bulk form.

2.21 CFR 1304.34(f)

Having determined the parameters within which competition is to analyzed, it is now appropriate to turn to that analysis. At the outset, the Acting Deputy Administrator questions whether competition can ever be considered adequate under 21 U.S.C. 952(a)(2)(B) when less than two firms manufacture the product in question. The Acting Deputy Administrator acknowledges that 21 CFR 1304.34(f) directs that ''the fact that the number of existing manufacturers is small shall not demonstrate, in and of itself, that adequate competition among them does not exist''. It is also noted that with no discussion, the Administrative Law Judge found that this section clearly prohibited a finding that competition is inadequate based solely on the fact that there is only one domestic manufacturer or bulk cocaine hydrochloride. However, the Acting Deputy Administrator notes that 21 U.S.C. 952(a)(2)(B) and 21 CFR 1304.34(f) clearly contemplate that there are at least two manufacturers of the controlled substance in question. Both provisions use plural language when referring to a relationship between manufacturers. Furthermore, the word ''competition'' is defined as being ''a struggle between rivals for the same trade at the same time''. Black's Law Dictionary 284 (Th ed. 1990). It is a ''contest between two rivals''. *Id.* (emphasis added).

3. The Factors of 21 CFR 1304.34(d)

Nonetheless, proceeding on the assumption that competition can exist for the purposes of 21 U.S.C. 952(a)(2)(B) when there is only one manufacturer, the Acting Deputy Administrator will analyze the adequacy of competition in the relevant market by considering the five factors enumerated in 21 CFR 1304.34(d).

a. 21 CFR 1304.34(d)(1): Price Rigidity. Title 21 of the CFR 1304.34(d)(1), directs the Acting Deputy Administrator to consider the ''extent of price rigidity in light of changes in (i) raw materials and other costs and (ii) conditions of supply and demand'' in determining the adequacy of competition. The only evidence in the record regarding Mallinckrodt's total actual costs are estimates prepared by Professor Leffler. Professor Leffler calculated ''upper bound'' and ''lower bound'' costs for Mallinckrodt. The ''lower bound'' costs were based upon Mallinckrodt's statement that the price it paid for crude cocaine was more than the price that Roxane's supplier (hereinafter Exporter) had committee to selling bulk cocaine hydrochloride to Roxane for importation. The ''upper bound'' costs were based upon the assumption that Mallinckrodt's crude cocaine costs equaled approximately eighty percent of its price. Professor Leffler based this assumption on his knowledge of profits in the pharmaceutical industry and that Roxane's profit as a percentage of total sales equaled approximately twenty percent. The remaining twenty percent represents Mallinckrodt's other costs, and its profit.

Using this methodology, Professor Leffler obtained an ''upper bound'' and ''lower bound'' estimate for the price Mallinckrodt paid for crude cocaine in 1983. Then, using Mallinckrodt's index of its cost for crude cocaine between 1983 and 1995, Professor Leffler obtained an estimate for the price Mallinckrodt paid for crude cocaine in subsequent years, ending in 1995. Professor Leffler than analyzed the available data to obtain estimates for all other costs Mallinckrodt would incur in its production and sale of bulk cocaine. In making this analysis, Professor Leffler assumed that in 1983, Mallinckrodt earned a ten percent profit rate on sales, a conservative figure that he arrived at based upon his knowledge of the generic drug business. He then inflated the estimates of these other costs over the subsequent years by using a price index for medical and botanical chemicals.

Professor Leffler's ''upper bound'' estimates reveal that between 1983 and 1995, the total costs incurred by Mallinckrodt in manufacturing crude cocaine rose 643 percent. Over the same period, Mallinckrodt's prices rose 2355 percent, resulting in a 30,796 percent increase in profit.

Professor Leffler's ''lower bound'' estimates demonstrate that between 1983 and 1995, the total cost incurred by Mallinckrodt in manufacturing crude cocaine rose at a rate of 359 percent. Over this same period, Mallinckrodt's prices rose 2355 percent, resulting in a 35,216 percent increase in profit.

The estimated costs and profits of Mallinckrodt, testified to by Professor Leffler, were not rebutted by Mallinckrodt. Mallinckrodt offered no cost or profit evidence into the record, other than the index of its cost for crude cocaine that Professor Leffler used in making his calculations. Upon motion of Roxane, the Administrative Law Judge drew and adverse inference that Mallinckrodt's costs and profits were at the midpoint of the range calculated by Professor Leffler in his ''lower bound'' and ''upper bound'' cost estimates, because Mallinckrodt refused to provide information regarding its costs and profits. The Acting Deputy Administrator has reviewed all arguments of the parties regarding the drawing of these adverse inferences and agrees with the findings of the Administrative Law Judge with respect to this issue. However, even if the drawing of these adverse inferences were improper, the Acting Deputy Administrator finds that Mallinckrodt has offered no credible evidence to rebut this testimony of Professor Leffler. Therefore, even without the adverse inferences, the Acting Deputy Administrator finds that the record establishes that between the years 1983 and 1995, Mallinckrodt's costs increased no more than 643 percent. During this same period, Mallinckrodt's prices increased 2,355 percent, resulting in a profit increase of no less than 30,796 percent.

Based upon this evidence, the Acting Deputy Administrator finds that Mallinckrodt's prices are rigid in light of changes in its costs.

Section 1304.34(d)(1) requires that prices be analyzed not only in light of changes in costs, but also in light of changes in supply and demand. The evidence in the record clearly supports a finding that there was a period in the late of 1980's when the demand for licit cocaine exceeded the supply. However, there is no evidence that this shortage continued after 1990. Rather, the evidence suggests, and Mallinckrodt has repeatedly argued, that the legitimate demand for cocaine has steadily declined. The United Nations International Narcotics Control Board's (UN) statistics reveal that legitimate consumption of cocaine in the United States declined approximately 36 percent from 1988 to 1995, and 13.5 percent between 1990 and 1995. Mallinckrodt's own witness testified that the United States' licit cocaine consumption declined from 500 kilograms to 300 kilograms between 1988 and 1995. In the face of this significant decline in legitimate demand for cocaine, Mallinckrodt's continued to increase its prices despite the end of the cocaine supply shortage of the late 1980's.

After the hearing before the Administrative Law Judge concluded on March 7, 1996, Mallinckrodt sought to introduce additional evidence regarding its sales and pricing of cocaine for fiscal year 1996 and 1997. The Administrative Law Judge declined to reopen the record to admit this evidence. However, as explained above, the Acting Deputy Administrator has decided that this information would be included in the rulemaking record.

Mallinckrodt's additional evidence demonstrates that in fiscal year 1996, its total sales of bulk cocaine declined 29% from 1995, resulting in a price decrease 12.9%. For fiscal year 1997, Mallinckrodt states that its total sales of bulk cocaine declined 36% from 1996, resulting in a price decrease of 16%. Mallinckrodt argues that it decreased its prices in 1996 and 1997 because of a decline in the legitimate demand for cocaine. The Acting Deputy Administrator finds this argument unpersuasive. As previously noted, the evidence received during the hearing revealed that the legitimate demand for cocaine has declined steadily since at least 1986. In the face of this decade-long decline in demand, Mallinckrodt took no action to reduce it prices. To the contrary, it drastically increased its prices, resulting in an extraordinary increase in profits. As decreasing demand did not impact on Mallinckrodt's pricing for the five years prior to the hearing on Roxane's application to be registered as an importer of cocaine, the Acting Deputy Administrator finds it more likely that Roxane's application, not the continued decline in the legitimate demand for cocaine, was the major impetus behind Mallinckrodt's decision to decrease its prices in 1996 and 1997.

Furthermore, Mallinckrodt would not sell cocaine at a loss. Therefore, the Acting Deputy Administrator also finds that the fact that Mallinckrodt is able to reduce its price for cocaine 27%, when there is no indication of decling costs, is further evidence that the overwhelming percentage of Mallinckrodt's price is profit.

Based upon the foregoing, the Acting Deputy Administrator finds that the evidence, when analyzed within the context of 21 CFR 1304.34(d)(1), heavily favors a finding that there is inadequate competition among the domestic manufacturers of bulk cocaine.

b.21 CFR 1304.34(d)(2): Shifting Market Share. Section 1304.34(d)(2) requires that the Acting Deputy Administrator consider ''[t]he extent of service and quality competition among the domestic manufacturers for share of the domestic market including (i) shifts in market shares and (ii) shifts in individual customers among domestic manufacturers.'' It is undisputed in the record that Mallinckrodt is the only domestic manufacturer of bulk cocaine. Hence, its share of the market has been one hundred percent since it entered the bulk cocaine market in 1983, and there has been no shifting of market share of individual customers.

Based upon the foregoing, the Acting Deputy Administrator finds that the evidence, when analyzed within the context of 21 CFR 1304.34(d)(2), favors a finding that there is inadequate competition among the domestic manufacturers of bulk cocaine.

c.21 CFR 1304.34(d)(3): Price Differentials: Section 1304.34(d)(3) requires that the Acting Deputy Administrator consider:

> The existence of substantial differentials between (i) domestic prices and (ii) the higher of prices generally prevailing in foreign markets or the prices at which the applicant for registration to import is committed to undertake to provide such products in the demos tic market in conformity with the Act. In determining the existence of substantial differentials hereunder, appropriate consideration should be given to any additional costs imposed on domestic manufacturers by the requirements of the Act and such other cost-related and other factors as the Administrator may deem relevant. In no event shall an importer's offering prices in the United States be considered if they are lower than those prevailing the foreign market or markets from which the importer is obtaining his supply.

The parties disagree as to whether Roxane could establish the ''prevailing prices'' in foreign markets without offering evidence of prices charged by more than one manufacturer of bulk cocaine in these markets. Mallinckrodt argues that because Roxane only provided evidence of the prices that Exporter charged in foreign markets, it failed to establish ''prevailing prices''. Roaxane argues that Exporter has competition from other manufacturers in the foreign markets and therefore, as testified to by its witness, its pricing must be comparable to that of the other manufacturers.

The record establishes that there is competition among manufacturers of bulk cocaine in these foreign markets. Roxane's witness, an officer of Exporter, testified that because of this competition, the price charged by Exporter for bulk cocaine in the relevant foreign markets is comparable to the price charged by other manufacturers of bulk cocaine. This is logical, and no evidence was submitted to rebut this statement. Therefore, after careful review of both arguments, the Acting Deputy Administrator agrees with the conclusion of the Administrative Law Judge and finds that the prices charged by Exporter in other countries are those generally prevailing in the countries in which it markets bulk cocaine.

Having determined that Roxane can establish prevailing prices by presenting evidence regarding one manufacturer's prices, it must now be determined if those prices, or the price at which Exporter has offered to sell Roxane bulk cocaine, is the appropriate one to compare with the domestic price of $31,000/kilogram of bulk cocaine. Roxane argues that it does not intend to ''offer'' bulk cocaine in the domestic market and therefore, the only comparison possible under 21 U.S.C. 1304.34(d)(3) is between the domestic price and the prices generally prevailing in the foreign market. The Acting Deputy Administrator finds Roxane's argument to have merit, and will compare domestic prices with those prices generally prevailing in foreign markets.

Two witnesses employed by Exporter testified to its prices for bulk cocaine in several countries. However, the prices testified to by one witness are higher than the prices testified to by the other witness. The difference is attributed to the fact that the first witness' figures were calculated using the sales of smaller size packages of cocaine, i.e.,

one, five and twenty-five grams, which are offered for sale at a higher price per kilogram than the larger packages. The second witness testified that his figure represented the average price per kilogram for cocaine sold in packages of one hundred grams or greater. No evidence was presented to rebut either the price testimony of these witnesses, or their testimony explaining the differences in those prices. As Roxane seeks to import bulk cocaine in one kilogram quantities, the Acting Deputy Administrator finds that it is most appropriate to use the schedule of prices for a kilogram of cocaine that was prepared using only the sales of cocaine in packages of one hundred grams or greater.

Using that schedule, the record establishes that the prevailing prices in foreign markets are between thirteen and twenty two percent of the domestic price for a kilogram of cocaine. Based upon these figures, the Acting Deputy Administrator finds that there is a substantial differential between the prices generally prevailing in the foreign markets and the domestic price. Alternatively, even if the Acting Deputy Administrator compared the price at which Exporter was committed to providing Roxane with bulk cocaine with domestic prices, he would still find a substantial differential existed between the two prices.

The significance of this substantial differential must be viewed in light of any additional costs imposed upon domestic manufacturers by the requirements of the Controlled Substances Act. Mallinckrodt, the only domestic manufacturer of bulk cocaine, had ample opportunity to provide evidence regarding costs which would mitigate the substantial differential between its prices and those generally prevailing in foreign markets, but no such evidence was submitted. Therefore, the Acting Deputy Administrator finds that based upon the record, the domestic manufacturer of cocaine does not incur any costs in complying with the Controlled Substances Act that would explain the extraordinary differential between its prices and those prevailing in foreign markets.

Mallinckrodt argues that it should not be penalized for refusing to disclose its confidential cost data, particularly when Exporter was not compelled to produce such information. However, the regulation specifically states that the domestic manufacturers' prices should be credited with regulatory or other costs when determining the significance of a substantial price differential. The costs of the foreign manufacturer would only be relevant to this analysis if the domestic manufacturers offered evidence of such costs. It would then be incumbent upon the foreign manufacturer to provide such cost data if it wanted to rebut this evidence, or mitigate its significance, by showing that it incurred similar costs.

Therefore, based upon the foregoing, the Acting Deputy Administrator finds that the evidence, when analyzed within the context of 21 CFR 1304.34(d)(3), favors a finding that there is inadequate competition among the domestic manufacturers of bulk cocaine.

d. 21 CFR 1304.34(d)(4): Competitive Restraints. Section 1304.34(d)(4) requires that the Acting Deputy Administrator consider ''[t]he existence of competitive restraints imposed upon domestic manufacturers by governmental regulations'' when analyzing the state of competition in the domestic market. The only such competitive restraint on domestic manufacturers of bulk cocaine is the general prohibition against importing coca paste contained in 21 U.S.C. 952(a). Mallinckrodt argues that this prohibition requires it to obtain its raw materials from Stepan, whose price for coca paste is greater than the price that Exporter has committed itself to providing Roxane with bulk cocaine. However, there is nothing in the record to suggest that Mallinckrodt could not file an application for registration to import coca paste pursuant to 21 U.S.C. 952(a)(2)(B).

Based upon the foregoing, the Acting Deputy Administrator finds that the evidence, when analyzed within the context of 21 CFR 1304.34(d)(4), favors a finding that there is inadequate competition among the domestic manufacturers of bulk cocaine.

e. 21 CFR 1304.34(d)(5): Other Relevant Factors. Finally, 21 CFR 1304.34(d)(5) provides that the Acting Deputy Administrator shall consider ''[s]uch other factors may be relevant to the determinations under this paragraph''. A review of the record reveals that there are several additional issues that need to be addressed.

First, Mallinckrodt has strenuously argued that the determination as to whether competition is adequate requires a balancing between the risks of diversion and the benefits of competition. In support of this argument, Mallinckrodt's economic expert testified that ''the adequate level of competition must represent an optimal balancing between the price reduction benefits of competition to patients and the diversion cost of competition to society, such that the public interest is maximized.''

It is reasonable to infer from an extensive review of the legislative history that Congress has already factored the risk of diversion into the statute by prohibiting the importation of certain controlled substances, except in very narrowly defined circumstances. One of the exceptions, of course, is where competition is inadequate among the domestic manufacturers of a particular controlled substance. Furthermore, where the risk of diversion is a relevant factor, it is specifically mentioned in the Controlled Substances Act and the regulations promulgating it. For example, 21 U.S.C. 823(a), and 21 CFR 1304.34(b)(1) and (5)(c) clearly mandate that the risk of diversion be considered in determining the ''public interest''. For these reasons, the Acting Deputy Administrator finds that Congress did not intend for the risk of diversion to be a factor in determining the adequacy of competition for purposes of 21 U.S.C. 952(a)(2)(B).

It has also been argued that allowing importation in this case would frustrate longstanding U.S. policy against the importation of finished controlled substances. In furthering this argument, the following passage from a Department of State monograph by Donald E. Miller, entitled ''Licit Narcotics Production and Its Ramifications for Foreign Policy'', dated August 1, 1980 was cited:

> The U.S. has been a traditional ''manufacturing'' country for about 75 years, whereby finished narcotics are manufactured by U.S. companies from imported raw materials. Economic and industrial patterns have developed in accordance with that practice, substantial funds, equipment and personnel have been committed by U.S. companies, and there is no good reason why the U.S. should jeopardize its industrial capability and financial interests.

Id. at 56.

Testimony of this nature by former and present employees of this agency was also offered to evidence this policy against the importation of finished narcotics.

At the outset, the Acting Deputy Administrator finds the reliance upon Mr. Miller's monograph as evidence of this policy to be misplaced. Mr. Miller was presenting an argument against amending 21 U.S.C. 952(a) to allow the importation of finished narcotics without having to make a showing that there is either an emergency situation or that competition among domestic manufacturers is inadequate.

Nonetheless, it is clear that Congress intended there to be a preference for the domestic manufacture of Schedule II controlled substances. This preference is embodied in the prohibition against

the importation of these substances contained in 21 U.S.C. 952(a)(1). It is equally clear, however, that Congress did not want to completely preclude the importation of these substances. Rather, it provided in 21 U.S.C. 952(a)(2) that under certain conditions, importation would be allowed. To argue that a policy against the importation of finished narcotics should take precedence over the statute is a request that this agency ignore the law. For this reason, the Acting Deputy Administrator finds that the preference for the domestic manufacture of Schedule II controlled substances is overcome if importation is warranted under 21 U.S.C. 952(a)(2).

It was also argued that allowing Roxane to import bulk cocaine would cause Mallinckrodt to exit the market, which would thwart this preference for the domestic manufacture of controlled substances. The Acting Deputy Administrator finds this argument unpersuasive. As already discussed, the Acting Deputy Administrator believes that this preference must give way when the conditions of 21 U.S.C. 952(a)(2)(B) are satisfied. Further, the evidence suggests that there is a significant amount of room for Mallinckrodt to reduce its prices and still make a profit. Finally, as mentioned earlier in this decision, there is nothing preventing Mallinckrodt from applying to be registered to import coca paste pursuant to 21 U.S.C. 952(a)(2)(B).

Based upon the foregoing, the Acting Deputy Administrator finds that none of these additional issues, considered pursuant to 21 CFR 1304.34(d)(5), warrant precluding the importation of bulk cocaine pursuant to 21 U.S.C. 952(a)(2)(B) if competition is deemed to be inadequate.

C. Decision Regarding the Adequacy of Competition Among the Domestic Manufacturers of Bulk Cocaine

The Acting Deputy Administrator has reviewed the entire record within the context of 21 CFR 1304 (d), (e) and (f), and has made the findings discussed above. As a result of these findings, the Acting Deputy Administrator concludes that competition among the domestic manufacturers of cocaine is inadequate.

D. Can Competition Be Rendered Adequate by Registering Additional Domestic Manufacturers of Bulk Cocaine

Mallinckrodt has argued that even if competition is found to be inadequate, it could be rendered adequate by the registration of additional domestic manufacturers because the process, equipment and raw materials are readily available, there are no regulatory barriers to entry, and there are numerous possible entrants.

Roxane argued that competition cannot be rendered adequate by the registration of additional domestic manufacturers because there are not current manufacturers of bulk cocaine other than Mallinckrodt, no other companies have ''formally'' applied for registration as manufacturers of bulk cocaine, and other producers of bulk narcotics have expressed no interest in becoming registered. Roxane further argues that DEA's prior interpretation of 21 U.S.C. 952(a)(2)(B) is that ''an importer need only address a current manufacturer's competition and that of any applicants to manufacture which have formally applied for registration''.

At the outset, the Acting Deputy Administrator believes that he is not only bound by the prior interpretation of this section by this agency, but that it is also the most reasonable interpretation. Besides Mallinckrodt, there is only one additional manufacturer registered to manufacture cocaine. However, the record indicates that this manufacturer is bankrupt and is not likely to manufacture cocaine in competition with Mallinckrodt.

Even if the Acting Deputy Administrator were to consider potential applicants as candidates for the manufacturing of bulk cocaine, the barriers to entry would preclude them from actually competing with Mallinckrodt. The Acting Deputy Administrator finds persuasive Professor Leffler's testimony that the necessary investment of several million dollars in manufacturing equipment and storage facilities would be a sufficient barrier in and of itself to the entry of a rational manufacturer into what Mallinckrodt has described as being a ''flat to declining market''. Furthermore, the evidence in the record clearly establishes that the manufacture and sale of bulk cocaine has been extremely profitable for Mallinckrodt. Despite the prospect of these tremendous profits, no other manufacturer has entered the market. This is further evidence that substantial barriers to their entry exist.

For the foregoing reasons, the Acting Deputy Administrator finds that the registration of additional manufacturers will not render competition in the domestic manufacturing market for bulk cocaine adequate.

III. The Adjudication

A. Introduction

Having determined that market conditions warrant the importation of cocaine hydrochloride pursuant to 21 U.S.C. 952(a)(2)(B), the remaining issue is whether Roxane's application for registration as an importer of cocaine hydrochloride should be granted. The Controlled Substances Act provides that the Acting Deputy Administrator shall register an applicant to import a schedule II substance if it is determined that such registration is in the public interest. 21 U.S.C. 958(a); 21 CFR 1304.34(b). In determining the public interest, the Acting Deputy Administrator must consider the factors listed in 21 U.S.C. 823(a)(1)–(6) and 21 CFR 1304.34(b)(1)–(5).

B. Public Interest Determination

1. Risk of Diversion v. Benefits of Competition

Pursuant to 21 U.S.C. 823(a)(1) and 21 CFR 1304.34(b)(1), the Acting Deputy Administrator is required to consider:

> (M)aintenance of effective controls against diversion of particular controlled substances * * *, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.

a. Adequacy of Competition. Consistent with his conclusion in the rulemaking aspect of this case, the Acting Deputy Administrator finds that the number of domestic manufacturers of bulk cocaine is insufficient to produce bulk cocaine under adequately competitive conditions, and cannot be rendered adequate by the registration of additional manufacturers. Therefore, the registration of an importer of cocaine is warranted under 21 U.S.C. 823(a)(1) and 21 CFR 1304.34(b)(1), if it is found that the applicant for registration will maintain effective controls against diversion.

b. Maintenance of Effective Controls Against Diversion. In making this determination, the Acting Deputy Administrator must consider whether the applicant complies with ''security requirements of 21 CFR 1301.71–1301.76''. and employs ''security procedures to guard against in-transit losses within and without the jurisdiction of the United States''. 21 CFR 1304.34(c).

The Government and Roxane both presented evidence that Roxane complies with the security requirements of 21 CFR 1301.71–1391,76. This evidence is credible and was unrebutted in the hearing. Therefore, the Acting Deputy Administrator finds that Roxane is in compliance with these security requirements. The Acting Deputy

Administrators agrees with the finding of the Administrative Law Judge that the current system of importing coca leaves for processing into cocaine in the United States is less susceptible to diversion that the importation of cocaine. However, the record establishes that Roxane and Exporter intend to employ security procedures sufficient to guard against in-transit losses.

Roxane and Exporter presented evidence of two plans that developed for transporting cocaine hydrochloride from Exporter's country to the United Stats. One method would utilize an established international delivery service, which would transport the cocaine from an airport in Exporter's country to an airport in the United States. Once in the United States, the cocaine would be transported by air to the airport closest to Roxane's facilities. The delivery service would then transport the cocaine by truck to Roxane's facilities. Utilizing this method, it would take approximately three days to transport the cocaine from Exporter to Roxane, including time for the package to clear U.S. Customs and possibly be subjected to inspection by the Food and Drug Administration.

In the second plan, Exporter will transport the cocaine from its facilities to the nearest international airport, under armed guard. Exporter's personnel will remain with the cocaine to witness its loading onto the aircraft and the taxiing of the aircraft away from the terminal. The aircraft will fly directly to one of three airports within driving distance of Roxane's facilities. The cocaine will be met by Roxane's personnel and be accompanied by them to U.S. Customs. This personnel will then witness the loading of the cocaine onto a truck, for nonstop transportation to Roxane's facilities. Utilizing this method, it would take approximately eighteen hours to transport the cocaine from Exporter to Roxane. This is Roxane and Exporter's preferred method of transportation.

In addition to the transportation plans, Roxane presented unrebutted evidence that there will be only one shipment a year, and this shipment will be scheduled to avoid having the cocaine in transit over a weekend or holiday. Further, packaging of the cocaine will be done in compliance with the agency's requirements.

Finally, both Roxane and Exporter have a vast amount of experience in dealing with controlled substances and preventing their diversion, and have excellent records of performance in this regard. Also, they are committed to working with this agency in implementing a plan which will minimize the risk of diversion while the cocaine is transit. For these reasons, the Acting Deputy Administrator finds that although no final plan has been settled upon for transporting the cocaine from Exporter to Roxane, Roxane and Exporter are committed to employing security procedures to guard against diversion of the cocaine shipments within and without of the jurisdiction of the United States.

2. Compliance With Applicable State and Local Law

Pursuant to 21 U.S.C. 823(a)(2) and 21 CFR 1304.34(b)(2), the Acting Deputy Administrator must consider whether the applicant for registration as an importer is in ''[c]ompliance with applicable State and local law'' in determining if granting the application will be in the public interest. Roxane officials testified that it is in compliance with all applicable laws, and no evidence was presented to rebut this testimony. Therefore, the Acting Deputy Administrator finds that Roxane has carried its burden with respect to this factor.

3. Promotion of Technical Advances

The Acting Deputy Administrator is required to consider the applicant's ''promotion of technical advances in the art of manufacturing these substances and the development of new substances'' in determining the public interest, pursuant to 21 U.S.C. 823(a)(3) and 21 CFR 1304.34(a)(3). Roxane put on uncontested evidence that it was the first manufacturer to market cocaine in a premixed topical solution. Prior to this, cocaine was marketed in flake and powder form, and the consumers were required to formulate their own solutions. Roxane's introduction of cocaine in premixed topical solutions provided the consumer with a more consistent quality in the product, and lowered the amount of waste and risk of diversion. For this reason, the Acting Deputy Administrator finds that Roxane has also carried its burden with respect to this factor.

4. Prior Conviction Record of Applicant

In determining the public interest, the Acting Deputy Administrator is required to consider the prior conviction record of the applicant for registration ''under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances''. It is undisputed in the record that Roxane has no such convictions, and therefore, the Acting Deputy Administrator finds that Roxane has carried its burden with respect to this factor.

5. Past Experience in the Manufacture of Controlled Substances and Controls Against Diversion

The record indicates that Roxane has been in the business of manufacturing controlled substances for years, and has an exceptional record for maintaining effective controls against the diversion of these substances, above and beyond what is required by law. Roxane's record in this regard is sufficient to find that it has met its burden with respect to this factor, despite Mallinckrodt's argument that Roxane has no experience in handling the international shipment of bulk cocaine.

6. Other Factors Relevant to Public Health and Safety

The only remaining issue in the determination as to whether granting Roxane's application to be registered as an importer of cocaine would be in the public interest is whether Exporter will be manufacturing the cocaine it will sell to Roxane from seized materials. This agency has a policy against the introduction of seized materials into the licit narcotics market, and the issue is one which must be given serious consideration.

A report from the United Nations stated that coca paste imported to Exporter's country from Peru in 1992 and 1993 was manufactured from seized materials. In the hearing, Mallinckrodt argued that this report illustrates that there is a serious risk that Roxane will be importing cocaine manufactured from seized materials. Therefore, granting Roxane's application to be registered as an importer of cocaine would be contrary to the public interest and violate long-standing policy against the use of seized materials for licit consumption.

In response, Roxane offered a letter that Exporter obtained from its supplier of coca paste regarding this issue. In this letter, Exporter's supplier certifies that it will provide Exporter with coca paste manufactured from coca leaves that are legally cultivated. However, the Acting Deputy Administrator agrees with the Administrative Law Judge that this letter is not sufficient to establish that all crude cocaine supplied to Exporter will be manufactured from legally cultivated materials.

Nonetheless, there is evidence in the record that a comprehensive forensic analysis can determine if cocaine is lawfully manufactured. Mallinckrodt argues that even if Roxane can determine if a certain shipment of cocaine is illicit, it cannot identify unknown impurities and eliminate them. However, as the Administrative

Law Judge suggests, this agency will require Roxane to certify that the cocaine it seeks to import is licit as a part of the import permit process. Therefore, the Acting Deputy Administrator finds that since chemical analysis can differentiate between licit and illicit cocaine, this agency will be able to prevent the introduction of cocaine manufactured from illicit materials into the licit domestic market for cocaine.

For the above-stated reasons, The Acting Deputy Administrator finds that granting Roxane's application to be registered as an importer of cocaine will not violate this agency's policy against the use of seized materials to satisfy the legitimate market for narcotics in this country.

7. Conclusion

Based upon the foregoing, the Acting Deputy Administrator finds that it is in the public interest, as defined by 21 U.S.C. 823 (a)(1)–(6) and 21 CFR 1304.34(b)(1)–(5), to grant Roxane's application to be registered as an importer of cocaine hydrochloride.

IV. Conclusion

As stated above, the Acting Deputy Administrator has determined that competition among the domestic manufacturers of bulk cocaine hydrochloride is inadequate, and will not be rendered adequate by registering additional domestic manufacturers under 21 U.S.C. 823. Therefore, the importation of cocaine hydrochloride, a Schedule II controlled substance, is hereby permitted, in amounts to be determined through the import permit procedures of 21 CFR part 1312.

Furthermore, the Acting Deputy Administrator has determined that Roxane's application to be registered as an importer of cocaine hydrochloride is in the public interest. As a result, the application is hereby granted. This decision is effective November 18, 1998.

Dated: October 6, 1998.

Donnie R. Marshall,

Acting Deputy Administrator.

[FR Doc. 98–27890 Filed 10–16–98; 8:45 am]

BILLING CODE 4410–09–M

NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

National Endowment for the Arts; National Council on the Arts 135th Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the National Council on the Arts will be held on October 30, 1998 from 9:00 a.m. to 4:30 p.m. in Room M–09 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW, Washington, D.C. 20506.

The meeting will be open to the public on a space available basis. Topics for discussion will include: Application Review (Creation & Presentation, Literature Fellowships, Leadership Initiatives, Policy Research & Technology), a presentation on Open Studio, a Congressional update, Guidelines (FY 99 ArtsREACH Initiative, FY 2000 Grants to Organizations; and FY 2000 Literature Fellowships), the FY 2000 budget, an update on the Endowment's Revised Strategic Plan 1999–2004, and general discussion.

If, in the course of discussion, it becomes necessary for the Council to discuss non-public commercial or financial information of intrinsic value, the Council will go into closed session pursuant to subsection (c)(4) of the Government in the Sunshine Act, 5 U.S.C. 552b. Additionally, discussion concerning purely personal information about individuals, submitted with grant applications, such as personal biographical and salary data or medical information, may be conducted by the Council in closed session in accordance with subsection (c)(6) of 5 U.S.C. 552b.

Any interested persons may attend, as observers, Council discussions and reviews which are open to the public. If you need special accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW, Washington, D.C. 20506, 202/682–5532, TTY–TDD 202/682–5429, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from the Office of Communications, National Endowment for the Arts, Washington, D.C. 20506, at 202/682–5570.

Dated: October 13, 1998.

Kathy Plowitz-Worden,

Panel Coordinator, Office of Guidelines and Panel Operations.

[FR Doc. 98–27968 Filed 10–16–98; 8:45 am]

BILLING CODE 7537–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Leadership Initiatives Advisory Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), as amended, notice is hereby given that a meeting of the Leadership Initiatives Advisory Panel (Millennium/Media section) to the National Council on the Arts will be held on October 19, 1998. The panel will meet via teleconference from 4:00 p.m. to 5:00 p.m. in Room 729 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW, Washington, D.C., 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of May 14, 1998, these sessions will be closed to the public pursuant to subsection(c)(4)(6) and (9)(B) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Panel Coordinator, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 682–5691.

Dated: October 15, 1998.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 98–28134 Filed 10–16–98; 8:45 am]

BILLING CODE 7537–01–M

NATIONAL SCIENCE FOUNDATION

Civil and Mechanical Systems Special Emphasis Panel

Special Emphasis Panel in Civil and Mechanical Systems; Notice of Meeting. In accordance with the Federal Advisory Committee Act Pub. L. 92–463, as amended, the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Civil and Mechanical Systems (1205).

Date and Time: November 2 and 3, 1998; 8:30 a.m. to 5:00 p.m.

Place: NSF, 4201 Wilson Boulevard, Rooms 530 and 580, Arlington, Virginia 22230.

Contact Person: Dr. Alison Flatau, Control, Materials and Mechanics Cluster, Division of Civil and Mechanical Systems, Room 545, NSF, 4201 Wilson Blvd., Arlington, VA 22230. 703/306–1361, x5069.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Aganda: To review and evaluate research proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information