INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–426 and 731–TA–984–985 (Final)]

Sulfanilic Acid From Hungary and Portugal

AGENCY: International Trade Commission.

ACTION: Revised schedule for the subject investigations.

EFFECTIVE DATE: May 30, 2002.

FOR FURTHER INFORMATION CONTACT: Gail Burns (202–205–2501), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS-ON-LINE) at *http://dockets.usitc.gov/eol/public.*

SUPPLEMENTARY INFORMATION: Effective on May 6, 2002, the Commission established a schedule for the conduct of the final phase of the subject investigations (**Federal Register** 67 FR 35832, May 21, 2002). The applicable statute directs that the Commission make its final injury determination within 45 days after the final determination by the U.S. Department of Commerce, which is September 18, 2002 (**Federal Register** 67 FR 36151, May 23, 2002). The Commission, therefore, is revising its schedule.

The Commission's new schedule for the investigations is as follows: requests to appear at the hearing must be filed with the Secretary to the Commission not later than September 17, 2002; the prehearing conference, if needed, will be held at the U.S. International Trade Commission Building at 9:30 a.m. on September 20, 2002; the prehearing staff report will be placed in the nonpublic record on September 11, 2002; the deadline for filing prehearing briefs is September 18, 2002; the hearing will be held at the U.S. International Trade Commission Building at 9:30 a.m. on September 24, 2002; the deadline for filing posthearing briefs is October 1, 2002; the Commission will make its final release of information on October 15, 2002; and final party comments are due on October 17, 2002.

For further information concerning these investigations see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

Issued: June 3, 2002

By order of the Commission.

Marilyn R. Abbott,

Secretary.

[FR Doc. 02–14329 Filed 6–5–01; 8:45 am]

BILLING CODE 7020–02–U

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Johnson Matthey, Inc.: Conditional Grant of Registration To Import Schedules II Substances

I. Background

Johnson Matthey, Inc., (Johnson Matthey) is registered with DEA to import phenyl acetone, a Schedule II controlled substance, and as a bulk manufacturer of a number of Schedule I and II substances, including oxycodone and hydrocodone. On December 23, 1998, Johnson Matthey submitted an application for renewal of its registration as an importer of Schedule II controlled substances. The application sought to renew Johnson Matthey's registration to import phenyl acetone, and to modify Johnson Matthey's registration to include importation of the narcotic raw materials concentrate of poppy straw (CPS) and raw opium (hereinafter referred to collectively as ''NRMs''). On December 23, 1998, Johnson Matthey also applied for renewal of its registration to manufacture Schedule I and II controlled substances in bulk. On April 9, 1999, DEA published notice of these applications in the **Federal Register.** The notices 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 applications and could also file a written request for a hearing on the applications in accordance with 21 CFR 1301.43.

In response to the publication, on May 10, 1999, both Mallinckrodt, Inc., (Mallinckrodt) and Noramco of Delaware, Inc., (Noramco) submitted comments, objections and requests for hearing in connection with Johnson Matthey's application to import NRMs. A Notice of Administrative Hearing, Summary of Comments and Objections was published in the Federal Register on December 3, 1999.

The requested hearing was held in Arlington, Virginia, from January 5, 2000, through January 13, 2000, before Administrative Law Judge Gail A. Randall. At the hearing, each party called witnesses to testify and introduced documentary evidence. After the hearing, each party submitted Proposed Findings of Fact, Conclusions of Law and Argument. The Antitrust Division of the Department of Justice filed a brief as amicus curiae. On September 21, 2000, the Administrative Law Judge issued her Recommended Rulings, Findings of Fact, Conclusions of Law and Decision, recommending that the Deputy Administrator issue a regulation permitting the importation of NRMs and that he conditionally grant Johnson Matthey's application for registration as an importer of NRMs. Both Noramco and Mallinckrodt filed exceptions to the Administrative Law Judge's Findings. Johnson Matthey filed a response to the exceptions, Johnson Matthey, Noramco and Mallinckrodt also submitted Reply Briefs to the brief of the Antitrust Division.

On September 21, 2000, the Administrative Law Judge certified and transmitted the record to the Deputy Administrator of DEA. The record included the Recommended Rulings, 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, the brief filed by the Antitrust Division of the Department of Justice, the reply briefs, motions filed by all counsel, all of the exhibits and affidavits, and the transcript of the hearing sessions.

II. Preliminary Matters

A. Regulatory Context

Because Johnson Matthey is applying for both a renewal of its registration and permission to import, this proceeding is a combined adjudication and rulemaking. The rulemaking determines whether Johnson Matthey may lawfully import into the United States the Schedule II controlled substances raw opium and CPS pursuant to 21 U.S.C. 952(a). Johnson Matthey has the burden of proof, and must establish by a preponderance of the evidence that such a rule can be issued. In order to do this,

Johnson Matthey must show by a preponderance of the evidence that the raw opium and CPS that it intends to import are necessary to provide for medical, scientific or other legitimate purposes.

The adjudication determines whether DEA should grant Johnson Matthey's application for registration as an importer of the Schedule II controlled substances raw opium and concentrate of poppy straw. In accordance with the DEA Statement of Policy and Interpretation on registration of importers, 40 FR 43,745 (1975), the Deputy Administrator will not grant Johnson Matthey's application unless Johnson Matthey establishes that the requirements of 21 U.S.C. § 958(a) and § 823(a) and 21 C.F.R. 1301.34(b)–(f) are met to show that Johnson Matthey's plans are in the public interest. DEA has the discretion to determine the weight assigned to each of the factors that must be considered to determine whether Johnson Matthey's registration to import will be granted. MD Pharmaceutical, Inc. v. DEA, No. 95–1267, 1996 U.S. App. LEXIS 1229 (D.C. Cir. 1996) (unpublished opinion.)

B. The Record

Nearly two months after the hearing, Johnson Matthey filed a Motion to Reopen the Record. In the motion, Johnson Matthey asked the court to allow into evidence the Report of the International Narcotics Control Board (INCB) for 1999. Among other things, the report contained information concerning the world-wide supply of opiate raw materials and consumption of opiates. Both Mallinckrodt and Noramco filed oppositions to the motion. By Memorandum and Order of March 15, 2000, the Administrative Law Judge denied Johnson Matthey's motion.

In an adjudication, the Deputy Administrator issues his final order based on the record made before the Administrative Law Judge. The Deputy Administrator has the authority, however, to request that the Administrative Law Judge reopen the record and admit evidence that was not introduced in the hearing. The party seeking to introduce such evidence must show, however, that the evidence was previously unavailable and is relevant to the issues in dispute. *Immigration and Naturalization Service* v. *Abudu,* 485 Y.S. 94 (1988).

There is no requirement, however, that the decision regarding the issuance of a regulation be made solely on the record. In a rulemaking, the purpose of the procedure is to gather evidence. As a result, the informal rulemaking proceeding does not end with the same degree of finality as does a formal adjudication. The Deputy Administrator may consider evidence submitted after the close of the comment period. *See Hoffman-La Roche, Inc.,* v. *Kleindienst,* 478 F.2d 1, 13–15 (3rd Cir. 1973). Nonetheless, at some point the agency must make a decision, and it is free to ignore comments that were filed late.

By Memorandum and Order of March 15, 2000, the Administrative Law Judge denied Johnson Matthey's motion to reopen the record. In reaching her decision, she noted that the record already contained much information derived from the INCB, information that was highly disputed during the hearing. She also found that the exclusion of the report ''does not fundamentally alter the core issues presented in this proceeding.''

With respect to both the adjudication and rulemaking aspects of this matter, the Deputy Administrator will not permit a reopening of the record to include the INCB report. While it appears that the report was unavailable until after the hearing, the report's relevance seems questionable in light of the Deputy Administrator's final decision in this matter, and the similar and highly disputed evidence already in the record.

C. Designations of Confidentiality

Pursuant to a Protective Order issued by the Administrative Law Judge on December 2, 1999, Mallinckrodt and Noramco requested that portions of the transcript of the hearing of this matter be designated as ''confidential'' or ''highly confidential.'' After the hearing, the parties were provided an opportunity to file by motion requests for the specific marking of the transcript. Noramco filed a Motion for Designation of Confidentiality and Mallinckrodt filed its Confidentiality Designations. In response, Johnson Matthey filed an Objection to Noramco and Mallinckrodt's Proposed Confidentiality Designations. Mallinckrodt then filed a Response to Objection of Johnson Matthey Inc. to Noramco's and Mallinckrodt's Inc.'s Proposed Confidentiality Designations.

By order of December 21, 2000, the Administrative Law Judge ruled on these motions, granting some of the requested designations of confidentiality and denying others. The Deputy Administrator has reviewed the pleadings on this issue, and hereby adopts the Administrative Law Judge's December 21, 2000, order.

III. Final Order

The Deputy Administrator has carefully reviewed the entire record in this matter, as defined above, and hereby issues this final rule and final order prescribed by 21 CFR 1316.67 and 21 CFR 1301.46, based upon the following findings and conclusions. The Deputy Administrator adopts the Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge in their entirety. They are incorporated into this final order as though they were set forth at length herein. The adoption of the judge's opinion 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.

A. The Rulemaking

As explained above, Johnson Matthey cannot be registered as an importer of NRMs unless the Deputy Administrator finds that Johnson Matthey will be allowed to import NRMs pursuant to 21 U.S.C. 952(a)(1). Because Johnson Matthey is the proponent of such a rule, it must establish by a preponderance of the evidence that such a rule can be issued.

21 U.S.C. 952 makes it unlawful to import controlled substances in Schedule I or II except that ''such amounts of crude opium, poppy straw, concentrate of poppy straw and coca leaves as the Attorney General finds to be necessary to provide for medical scientific or other legitimate purposes.'' Whether Johnson Matthey's importation of opium and poppy straw is ''necessary'' was highly disputed at the hearing of this matter.

Peter Bensinger, a former Administrator of DEA, testified that United States policy prohibits the cultivation or production of NRMs in the United States in favor of imports, in order to limit the potential diversion problems of domestic cultivation and production. Gerald Dumont, a consultant to the INCB, testified that he believed that the major suppliers of NRM would be willing to sell to Johnson Matthey, if registered. Mr. Dumont also believed that the registration of Johnson Matthey would not cause shortages, price increases or any change to the total U.S. allocation of NRMs. Dr. William Beaver, a physician and expert in pharmacology, testified that the derivatives manufactured from NRMs are necessary to the United States medical community, as there are medical demands that cannot be met by non-opiate narcotics. Dr. Beaver also testified that opiate pharmaceuticals have a long history of medical use and the medical community continues to rely upon opium-derived alkaloids rather than synthetic opiate analgesics.

These alkaloids and their semi-synthetic derivatives such as a hydromorphone, hydrocodone, and oxycodone are critical therapeutic agents today. Dr. Beaver concluded that morphine, codeine, hydromorphone, hydrocodone and oxycodone are necessary to the United States medical community.

Mallinckrodt and Noramco asserted that they have maintained an adequate and uninterrupted supply of opiate pharmaceuticals from their processing of opium and CPS. Therefore, in their opinion, Johnson-Matthey's importation of such substances is not ''necessary,'' as required by 21 U.S.C. § 952. They also argued that the statutory scheme required a full blown inquiry into the adequacy of competition among existing manufacturers.

As the Administrative Law Judge explained, the term ''necessary'' is not defined in the Controlled Substances Act. The ''necessary'' standard, however, has been employed since the inception of narcotics legislation. Moreover, the legislative history shows that the prohibition of 21 U.S.C. § 952 was intended to reduce diversion of illicit drugs, while the exception was intended to supply the drugs required by the medical community. There is nothing in the legislative history that would support any intention to limit the number of importers under the statute. Indeed, any such interpretation would mean that if the needs for NRMs could be satisfied by one company, no other companies would be allowed to import the raw materials. There is no evidence, however, that Congress intended this provision to create a monopoly for a single company. Nor does the legislative history show any concern with competition among NRM importers. Accordingly, for purposes of this rulemaking, the economic data supplied by the parties is not relevant.

Based upon the above, the Deputy Administrator finds that Johnson Matthey has met its burden of proof in showing that its proposed importation of NRMS is ''necessary'' to provide for legitimate medical purposes.

B. The Adjudication

Federal law prohibits the cultivation of the opium poppy in the United States, and also generally prohibits the importation of bulk narcotic alkaloids such as morphine and codeine. The NRMs raw opium and CPS therefore must be imported into the United States for purposes of extracting morphine and codeine for pharmaceutical use. Following the extraction of these alkaloids, the manufacturers convert them into active pharmaceutical ingredients (APIs), such as oxycodone and hydrocodone. These APIs are then sold to other manufacturers to produce either dosage formulations or other APIs. The formulated drugs are then sold to drug wholesalers or directly to health care entities.

Johnson Matthey, Noramco and Mallinckrodt are currently registered with DEA as bulk manufacturers of a number of Schedule I and II substances, including the Schedule II controlled substances oxycodone and hydrocodone. Noramco and Mallinckrodt are the only companies registered with DEA, however, as importers of NRMs and bulk manufacturers of codeine and morphine.

Since Johnson Matthey is not registered to import NRMs, it cannot manufacture its own codeine and morphine, but must purchase these compounds from Noramco and Mallinckrodt. In recent years, Noramco has been unwilling or unable to supply Johnson Matthey with all of the codeine and morphine that Johnson Matthey has requested. Johnson Matthey has applied with DEA to be registered as an importer of NRMs, so that the company can manufacture its own codeine and morphine. Noramco and Mallinckrodt oppose Johnson Matthey's application.

Pursuant to 21 U.S.C. 958a, and 823(a), DEA is required to register Johnson Matthey as an importer and manufacturer of Schedule I and II substances if the registration is ''consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In 823(a)(1)–(6). See also 21 C.F.R. 1301.34(b)(1)–(6)(i). Accordingly, the Deputy Administrator will first consider United States obligations under international treaties, then each of the factors delineated in 21 C.F.R. 1301(b)(1)–(6)(i), as follows.[1]

1. Treaty Obligations

There is no evidence that the importation of NRMs by Johnson Matthey would be inconsistent with United States obligations under international treaties, conventions or protocols. Under the treaty Single Convention on Narcotic Drugs, 1961, the United States is obligated to take all necessary measures to ensure that the international movement of narcotics is limited to legitimate medical and scientific needs. Peter B. Bensinger, former Deputy Administrator of DEA, credibly testified that the primary goal of the Single Convention and relevant United States drug policy is to encourage production of NRMs only in countries that can control the illicit diversion of these substances. DEA has developed a quota system to meet, in part, the obligations of the United States under this treaty. This ''80/20 rule,'' which requires the United States to purchase at least 80 percent of its NRMs from India and Turkey, is designed to achieve the goal of the Single Convention treaty. There is no evidence that entry of Johnson Matthey into the market for importation of NRMs would contravene this rule.

2. Maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate, medical, scientific, research or industrial channels, by limiting the importation of and bulk manufacture of such controlled substances to a number of establishments which can product an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific research, and industrial purposes.

As the Administrative Law Judge noted, DEA has previously interpreted identical language in the context of analyzing an application for manufacturing a Schedule I and Schedule II controlled substance as follows: ''The Drug Enforcement Administration of the United States Department of Justice, presently interprets the statute as requiring the registration of otherwise qualified applicants to manufacture any controlled substance as long as the total number of registrants remains within the effective control by the Administration. We believe that (this section of the statute) permits the Drug Enforcement Administration to restrict entry to a number of registrants constituting adequate competition only when actually necessary to maintain effective controls against diversion.'' Bulk Manufacture of Schedule I and II Substance, 39 Fed. Reg. 12,138 (DEA 1974).

Furthermore, DEA has written that, stated conversely, DEA is ''required to register an applicant who meets all the other statutory requirements, without regard to the adequacy of competition, if the Administration determines that registering another manufacturer will not increase the difficulty of maintaining effective controls against

[1] In this proceeding, Johnson Matthey, as the applicant, has the burden of proof of showing that the public interest will be served by its registration to import NRMs. 21 C.F.R. 1301.44(c). Noramco and Mallinckrodt, however, have the burden of proving and propositions of fact or law asserted by them in the hearing. *Id.; Roxane,* 63 Fed Reg. 55,891 (DEA 1998).

diversion.'' *Id.*6 Accordingly, the Deputy Administrator finds that if DEA determines that there would be no increased difficulty in controlling diversion, the requirements of this provision are satisfied, and an analysis of adequate competition is not required.

At the hearing, Noramco and Mallinckrodt attempted to show that Johnson Matthey's registration as an importer of NRMs would cause further diversion of controlled substances and a potential interruption in the supply of NRMs. Michael Misolovich, a Mallinckrodt executive, testified that if Johnson Matthey was inefficient in extracting narcotics from NRMs, its entry into the market would exaggerate legitimate demand, resulting in more cultivation of NRMs than is necessary and thereby increasing the risk of diversion. Richard A. Hoyt, another Mallinckrodt executive, testified that registration of Johnson Matthey could trigger a shortage of NRMs if Johnson Matthey were inefficient in processing NRMs.

The Deputy Administrator finds that neither Mallinckrodt nor Noramco offered any solid evidence in support of the view that registration of Johnson Matthey to import NRMs would cause increased diversion or a shortage of NRMs. Mr. Misolovich admitted that only basis for his allegation that Johnson Matthey would be inefficient in processing NRMs was based solely on the fact that Johnson Matthey had not processed NRMs in the past. Indeed, none of the evidence offered in support of these contentions rose above mere speculation. As noted above, Gerard Dumont, a gentleman with 30 years experience in the international market for NRMs, testified that the registration of Johnson Matthey would not cause shortages, price increases, or any change to the total U.S. allocation of NRMs. David Connor, an employee of Johnson Matthey with twelve years experience in purchasing NRMs on the world market, testified that supplied of NRMs from India, Turkey and other countries would be adequate to meet Johnson Matthey's needs. Mr. Connor testified further that Johnson Matthey's entry into the market would not result in an increase in the demand for NRMs, but would simply result in the displacement of NRMs from one buyer to another. Furthermore, the Deputy Administrator notes that neither Mallinckrodt nor Noramco has been unable to supply its customers with sufficient product during the ''shortages'' of NRMs over the past several years.

With regard to Johnson Matthey's efficiency in processing NRMs, Frank Stermitz, Ph.D., a professor of chemistry, testified credibly that the extraction of alkaloids from opium was a simple, uncomplicated and well established procedure known for 200 years, and that permitting Johnson Matthey to import NRMs would pose little danger to the world supply of NRMs. Other witnesses testified credibly that Johnson Matthey's registration as an importer of NRMs would not cause an increase in Indian production, but would simply redistribute the same amount of product among three, rather than two, companies.

Based upon the above, the Deputy Administrator finds that both Noramco and Mallinckrodt have failed to meet their burdens of proof to show that registration of Johnson Matthey as an importer of NRMs would increase diversion of controlled substances or cause an interruption in the supply of NRMs. Accordingly, the Deputy Administrator need not conduct an analysis of adequate competition.[2]

3. Compliance with applicable State and local law;

David M. Connor testified that Johnson Matthey has never been convicted of any offense relating to controlled substances under either Federal or State Law, and that Johnson Matthey complies with all New Jersey laws relating to controlled substances. There is nothing in the record to contradict this assertion.

4. Promotion of technical advances in the art of manufacturing these substances and the development of new substances.

Johnson Matthey has developed a patent that permits the manufacture of hydrocodone in a one-step process and has four other patent applications pending. It has also filed a patent application in Europe for the production of thebaine, a precursor to oxycodone. Thus it appears that Johnson Matthey promotes technical advances in the manufacturing of oxycodone and hydrocodone.

5. Prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;

David Conner testified without contradiction that Johnson Matthey has never been convicted of any offense relating to controlled substances under Federal or State law.

6. Past experience in the manufacture of controlled substances and the existence in the establishment of effective control against diversion.

Johnson Matthey has been registered by DEA as a manufacturer of Schedule I, II, and III controlled substances since 1985. Forrest F. K. Sheffy, Ph.D., a Johnson Matthey employee, testified that Johnson Matthey was founded in 1817 as a precious metals company, and has grown into a large, international corporation with businesses in numerous fields, including the manufacture of active pharmaceutical ingredients for sale to pharmaceutical companies. Mr. Sheffy also testified that Johnson Matthey today is a leader in the manufacture of controlled substances for use in pharmaceuticals.

A DEA Diversion Investigator (DI), testified that he conducted a 303 analysis of Johnson Matthey. The DI credibly concluded that Johnson Matthey's record keeping and security practices were in compliance with relevant law and regulation. DEA's Chief of the Drug Operations Section, Office of Diversion Control, credibly testified that his office found no reason why DEA should not grant the application of Johnson Matthey to import raw opium and CPS.

Johnson Matthey also hired former DEA agent, to conduct a review of the security of its physical plant and of its standard operating procedures. The former agent credibly testified that Johnson Matthey is in compliance with DEA regulations to prevent diversion with respect to the handling of controlled substances.

David Connor is responsible for Johnson-Matthey's compliance with DEA regulations. He previously worked for Noramco, and has 15 years experience in DEA compliance issues. At the hearing, he testified that Johnson Matthey is committed to the ''highest level of compliance with DEA regulations.'' Since he has worked for Johnson Matthey, there have been three on-site visits by DEA inspectors, without any violations. In the fourth quarter of 1998, DEA conducted an on-site inspection of the Johnson Matthey plant in New Jersey. At the end of the inspection the DEA investigator advised him that she had found no violations of DEA regulations, and since that time Johnson Matthey has received no notice of violations from DEA.

Accordingly, the Deputy Administrator finds that Johnson Matthey has had sufficient experience in the manufacture of controlled substances. The Deputy Administrator also finds that Johnson Matthey is in compliance with DEA regulations,

[2] The Deputy Administrator also finds that even if he had found that competition in the market for codeine phosphate and morphine sulfate was adequate, he would still find it appropriate to register Johnson Matthey as an importer of NRMs, since each of the other factors to be considered in determining the public interest weigh in Johnson Matthey's favor.

maintain effective controls against diversion of controlled substances and Johnson Matthey's importation of NRMs will not increase the risk of diversion of these substances for illicit uses.

7. Such other factors as may be relevant to and consistent with the public health and safety.

As the Administrative Law Judge noted, registration of Johnson Matthey as an importer of NRMs would also serve the public interest as further assurance that opiate pharmaceutical products such as oxycodone and hydrocodone will be available to the public. At present, all pharmaceuticals derived from NRMs in this country are manufactured by only two companies. Adding a third company would reduce the risk of supply problems in the event of regulatory recalls, fire, flood or other natural disasters.

8. Conclusion

Based upon the foregoing, the 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)–(6)i to grant Johnson Matthey's application to be registered as an importer of NRMs.

C. Exceptions

Both Noramco and Mallinckrodt filed exceptions to the Administrative Law Judge's Recommended Ruling, Findings of Fact, Conclusions of Law and Decision. Johnson Matthey responded to those exceptions. Having considered the record in its entirety, including the parties' exceptions and responses, the Deputy Administrator finds no merit in Noramco and Mallinckrodt's exceptions, many of which concerned matters that were addressed at length at the hearing. The exceptions were extensive and are part of the record. Only some of the exceptions merit further discussion, and they will not be restated at length herein.

In its exceptions, Normaco contends that licensing Johnson Matthey to import NRMs will ''dramatically'' weaken the standards for such licensing. Noramco claims that granting Johnson Matthey a license before the company has demonstrated that it is immediately prepared to start processing NRMs will create a standard by which any company will be able to obtain a license to import NRMs. This argument has no merit. Johnson Matthey has not yet constructed a new facility to process NRMs, but plans to do so in the near future. Furthermore, Johnson Matthey has had extensive experience in manufacturing controlled substances. Moreover, DEA's licensing of Johnson Matthey will be contingent upon Johnson Matthey's providing to DEA, prior to the receipt of the first shipment of NRMs, sufficient information concerning its facilities and procedures.

Noramco also contends that the Administrative Law Judge failed to correctly balance the risk of diversion that will result from the licensing of Johnson Matthey to import NRMs. This argument also has no merit. On the contrary, the Administrative Law Judge made extensive findings concerning the issue of potential diversion. The Administrative Law judge correctly stated that both Mallinckrodt and Noramco, without offering any specific evidence, speculated that merely permitting another party to import NRMs increases the risk that those NRMs will be diverted, on both the national and international level. The Administrative Law Judge found that Johnson Matthey has had a great deal of experience in handling opiate-derived compounds, without any alleged violations of DEA security regulations, and the The DI testified at the hearing that he had inspected Johnson Matthey's facilities and concluded that its security plans and practices comport with DEA regulations. Accordingly, the Deputy Administrator finds that there is no evidence that the licensing of Johnson Matthey to import NRMs would result in diversion of controlled substances.

In its exceptions, Mallinckrodt contends that the Administrative Law Judge erred in her finding that Johnson Matthey intends to import both CPS and raw opium. As evidence of Johnson Matthey's alleged intent only to import CPS, Mallinckrodt points to the fact that Johnson Matthey has only allocated $10 million to building a new facility to process NRMs. With little discussion, Mallinckrodt's witnesses testified that a plant to process both CPS and raw opium would required two separate lines and would cost more than $10 million. Mallinckrodt failed to demonstrate, however, that Johnson Matthey would be unable to process both raw opium and CPS. The Deputy Administrator finds that Johnson Matthey is still in the preliminary stages of its importation and processing of NRMs. If it turns out that the projected costs are greater than expected, there is no evidence that Johnson Matthey would fail to allocate sufficient funds to process both raw opium and CPS. Indeed, Forrest K. Sheppy, a Johnson Matthey executive, testified that the company was committed to expending the necessary sums to install an appropriate manufacturing facility.

Mallinckrodt also contends that the Administrative Law Judge, in her determination that an analysis of adequacy of competition was not necessary in this matter, erred in applying a DEA policy statement that referred to the manufacturing, rather than the importation, of controlled substances. In the policy statement, DEA stated that it interpreted the language of 21 U.S.C. 823(a)(1) to permit DEA to restrict entry to a number of registrants constituting adequate competition only when actually necessary to maintain effective controls against diversion. Mallinckrodt's argument has no merit. As the Administrative Law Judge stated, she found the statement of policy ''instructive'' rather than ''determinative.'' Moreover, the policy statement interpreted the exact same standards at issue here. Pursuant to 21 U.S.C. 958, in determining whether a license to import is in the public interest, the Deputy Administrator must look to the standards applicable to manufacturers at 21 U.S.C. 823. Thus for purposes of determining whether the importation or manufacture of controlled substances is in the public interest, Congress, in enacting the statute, made clear that both importers and manufacturers are to be treated alike in determining the public interest will be served.

IV. Conclusion

The Deputy Administrator concludes that, except for one factor, Johnson Matthey has satisfied all of the factors to be considered in both a rulemaking and adjudication to permit registration of Johnson Matthey to import NRMs. The unsatisfied factor concerns the fact that Johnson Matthey's proposal to import NRMs is not now adequately supported by concrete pans or proposals regarding the location and type of processing facility that it intends to use in processing NRMs. Johnson Matthey has neglected to produce sufficient evidence to show that its intended facility will substantially comply with requirements. The Deputy Administrator agrees with the Administrative Law Judge that this is not an insurmountable obstacle, however, and pursuant to the authority vested in him by 21 U.S.C. 952 and 958 and 28 CFR 0.100(b), hereby grants Johnson Matthey a conditional registration until such time as Johnson Matthey's facilities are complete and DEA can complete its requisite physical security and record keeping evaluation to ensure Johnson Matthey's continued protection of NRMs against diversion. The Deputy Administrator also finds that Johnson Matthey should provide DEA with a timetable of its proposed activities and submissions so that DEA

may plan for the prompt scheduling of its inspection and review activities. This decision is effective July 8 2002.

Dated: May 22, 2002.

John Brown III.

Deputy Administrator.

[FR Doc. 02–14218 Filed 6–5–02; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: Notice of Immigration Pilot Program.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The INS published a notice in the **Federal Register** on March 4, 2002 at 67 FR 9782. The notice allowed for a 60-day public review and comment period on the extension of a currently approved information collection. No public comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until July 8, 2002. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Department of Justice Desk Officer, 725—17th Street, NW., Room 10235, Washington, DC 20530.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other form of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Notice of Immigration Pilot Program.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* No Agency Form Number (File No. OMB–05); Adjudications Division, Immigration and Naturalization Service.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This collection of information is used by the INS to determine participants in the Pilot Immigration Program provided for by section 610 of the Appropriations Act. The INS will select regional center(s) that are responsible for promoting economic growth in a geographical area.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 50 responses at 40 hours per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 2,000 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact Richard A. Sloan, 202–514–3291, Director, Regulations and Forms Services Division, Immigration and Naturalization Service, U.S. Department of Justice, Room 4034, 425 I Street, NW., Washington, DC 20536. Additionally, comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time may also be directed to Mr. Richard A. Sloan.

If additional information is required contact: Mr. Robert B. Briggs, Clearance Officer, United States Department of Justice, Information Management and Security Staff, Justice Management Division, Patrick Henry Building, 601 D Street, NW., Ste. 1600, Washington, DC 20530.

Dated: May 28, 2002.

Richard A. Sloan,

Department Clearance Officer, United States Department of Justice, Immigration and Naturalization Service.

[FR Doc. 02–14198 Filed 6–5–02; 8:45 am]

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DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: Notice of information collection under review: guidelines on producing master exhibits for asylum applications.

The Department of Justice, Immigration and Naturalization Service (INS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on March 19, 2002 at 67 FR 12584, allowing for a 60-day public comment period. No comments were received by the INS on this proposed information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until July 8, 2002. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the items contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs 725—17th Street, NW., Washington, DC 20530; Attention: Department of Justice Desk Officer, Room 10235.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,