	Sep 2004 (MMBtu)	Oct 2004 (MMBtu)	Nov 2004 (MMBtu)	Dec 2004 (MMBtu)
Ute Tribal Leases in the Uintah and Ouray Reservation	4.37	4.46	6.57	6.03

For information on how to report additional royalties due to major portion prices, please refer to our Dear Payor letter dated December 1, 1999, on the MMS Web site address at *http://www.mrm.mms.gov/ReportingServices/PDFDocs/991201.pdf.*

Dated: January 17, 2006.

Shirley M. Conway,

Acting Associate Director for Minerals Revenue Management.

[FR Doc. E6–2690 Filed 2–24–06; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Capital Region; Carter G. Woodson Home National Historic Site, Designation as a Unit of the National Park System

AGENCY: National Park Service, Interior.

ACTION: Designation of Carter G. Woodson Home National Historic Site, Washington, DC as a unit of the National Park System.

SUMMARY: Under and by virtue of the authority conferred upon the Secretary of the Interior by section 3 of the Carter G. Woodson Home National Historic Site Act of December 19, 2003 (117 Stat. 2873), the property at 1538 Ninth Street, NW., Washington, DC, with the structure thereon, is established and designated a unit of the National Park System having the name ''Carter G. Woodson Home National Historic Site.'' The administration, protection and development of this national historic site shall be exercised by the National Park Service in accordance with the provisions of the authorizing legislation as well as laws generally applicable to units of the National Park System, including the Act of August 25, 1916 (16 U.S.C. 1, 2–4) and the Act of August 21, 1935 (49 Stat. 666; 16 U.S.C. 461–467). Warning is expressly given to all unauthorized persons not to appropriate, injure, destroy, deface, or remove any feature of this historic site.

DATES: February 27, 2006 is the date of the establishment of the Carter G. Woodson Home National Historic Site in accordance with Public Law 108–192 (117 Stat. 2873, December 19, 2003).

ADDRESSES: The Carter G. Woodson Home National Historic Site is administered as a site under the management of the Superintendent, National Capital Parks—East, 1900 Anacostia Drive, SE., Washington, DC 20020.

FOR FURTHER INFORMATION CONTACT: Superintendent Gayle Hazelwood, National Capital Parks—East, 1900 Anacostia Drive, SE., Washington, DC 20020, Telephone (202) 690–5185.

SUPPLEMENTARY INFORMATION: Whereas the Congress of the United States has declared it to be a national policy to preserve for the public use historical sites, buildings, and objects of national significance for the inspiration and benefit of the people of the United States, and whereas the Congress has recognized that:

(1) Dr. Carter G. Woodson, cognizant of the widespread ignorance and scanty information concerning the history of African Americans, founded on September 9, 1915, the Association for the Study of Negro Life and History, since renamed the Association for the Study of African-American Life and History.

(2) The Association was founded in particular to counter racist propaganda alleging black inferiority and the pervasive influence of Jim Crow prevalent at the time.

(3) The mission of the Association was and continues to be educating the American public of the contributions of Black Americans in the formation of the Nation's history and culture.

(4) Dr. Woodson dedicated nearly his entire adult life to every aspect of the Association's operations in furtherance of its mission.

(5) Among the notable accomplishments of the Association under Dr. Woodson's leadership, Negro History Week was instituted in 1926 to be celebrated annually during the second week of February. Negro History Week has since evolved into African American History Month.

(6) The headquarters and center of operations of the Association was Dr. Woodson's residence, located at 1538 Ninth Street, NW., Washington, DC.

Congress, therefore, on October 24, 2000, directed a resource study of the Dr. Carter G. Woodson Home and headquarters of the Association for the Study of African-American Life and History, located at 1538 Ninth Street, NW., Washington, DC, to identify the suitability and feasibility of designating the Carter G. Woodson Home as a unit of the National Park System.

Upon its consideration of that completed study and the recommendation of the Secretary of the Interior (Secretary) that the Carter G. Woodson Home should be made a unit of the National Park System, the Congress directed to the Secretary to establish the Carter G. Woodson Home National Historic Site as a unit of the National Park System by publication of a notice to that effect in the **Federal Register** upon the acquisition of the Carter G. Woodson Home. The Secretary was granted authority to acquire the Carter G. Woodson Home and any of three properties immediately to its north located at 1540, 1542, and 1544 Ninth Street, NW., described on the map entitled ''Carter G. Woodson Home National Historic Site'', numbered 876/82338–A and dated July 22, 2003.

Dated: February 17, 2006.

Gale A. Norton,

Secretary of the Interior.

[FR Doc. 06–1732 Filed 2–24–06; 8:45 am]

BILLING CODE 4312–JK–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Chattem Chemicals, Inc.: Grant of Registration To Import Schedule II Substances

I. Background

On February 9, 2002, Chattem Chemicals, Inc. (Chattem) applied to the Drug Enforcement Administration (DEA) for registration under 21 U.S.C. 958(a) as an importer of the narcotic raw materials (NRMs) raw opium, concentrate of poppy straw (CPS) and thebaine, all of which are Schedule II controlled substances.[1]

Pursuant to 21 CFR 1301.34(a), Mallinckrodt, Inc. (Mallinckrodt), Penick Corporation (Penick) and Noramco of Delaware, a Division of Ortho McNeil, Inc. (Noramco), requested a hearing on Chattem's application for registration as an importer of NRMs. The United States

[1] Chattem later withdrew its request for registration to import thebaine. In December 2001, DEA granted Chattem a registration as a bulk manufacturer of, among other controlled substances, codeine, morphine, thebaine and oxycodone.

Department of Justice, Drug Enforcement Administration (DEA or the Government) also participated as a party to the proceeding.

A hearing before a DEA Administrative Law Judge (ALJ) was held in Arlington, Virginia, in September and October 2002, and January 2003, with Chattem, Penick, Noramco, Mallinckrodt and the Government (the Objectors) participating and represented by counsel. All parties called witnesses to testify and introduced documentary evidence. After the hearing, the parties filed proposed findings of fact, conclusions of law and argument, and reply briefs.

Pursuant to 21 CFR 1301.44(c), Chattem has the burden of proof to show that it has met the statutory and regulatory requirements to import NRMs. The other parties to the proceeding have the burden of proving any propositions of fact or law asserted by them. *See Penick Corporation, Inc., Grant of Registration to Import Schedule II Controlled Substances*, 68 FR 6947, 6948 (DEA 2003).

On January 13, 2005, the ALJ filed an Opinion and Recommended Ruling, Findings of Fact, Conclusions of Law and Decision (ALJ Opinion). The ALJ recommended that Chattem's application be granted. All of the parties filed exceptions to the ALJ's recommended decision. Chattem filed a response to the exceptions filed by Mallinckrodt and Noramco.

After considering all of the evidence and post hearing submissions, The Deputy Administrator adopts, in part, the ALJ Opinion, makes independent findings, and rejects all contradictory findings and conclusions as unsupported by a preponderance of the evidence. The Deputy Administrator adopts all of the ALJ's decisions on motions filed during this proceeding, other than those that were overruled in the Deputy Administrator's Final Orders on the interlocutory appeals filed in this matter.[2]

All of the foregoing is incorporated into this Final Order as though set forth at length herein. The Deputy Administrator also incorporates by reference the Deputy Administrator's earlier decisions on the interlocutory appeals filed in this proceeding. Except as expressly noted herein, those parts of the ALJ's opinion adopted by the Deputy Administrator are in no manner diminished by any recitation of facts, issues and conclusions herein, or by any failure to mention a matter of fact or law.

II. Preliminary Matters

Regulatory Context

Because Chattem is applying for both a registration and permission to import, this proceeding is a combined adjudication and rulemaking. The rulemaking determines whether Chattem may lawfully import NRMs into the United States pursuant to 21 U.S.C. 952(a). Chattem 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, Chattem must show by a preponderance of the evidence that the NRMs that it intends to import are ''necessary'' to provide for medical, scientific or other legitimate purposes.

The adjudication determines whether DEA should grant Chattem's application for registration as an importer NRMs. 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 Chattem's application unless Chattem establishes that the requirements of 21 U.S.C. 958(a) and 823(a) and 21 CFR 301.34(b)(1)–(7) are met to show that Chattem's registration to import is 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 Chattem's registration to import will be granted. *MD Pharmaceutical, Inc.* v. *DEA*, No. 95–1267, 1996 U.S. App. LEXIS 1229 (DC Cir. 1996) (unpublished opinion.)

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.

A. The Rulemaking

As explained above, Chattem cannot be registered as an importer of NRMs unless the Deputy Administrator finds that Chattem will be allowed to import NRMs pursuant to 21 U.S.C. 952(a)(1). Because Chattem 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(a)(1) makes it unlawful to import controlled substances in Schedule I or II except ''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 Chattem's importation of NRMs is ''necessary'' was disputed at the hearing of this matter. Some of the Objectors argued that they as a group are able to import all necessary NRMs necessary to provide for medical, scientific or other legitimate purposes.

The ALJ found that it is undisputed that Chattem seeks to import NRMs for legitimate uses. The ALJ also noted that the actual amounts of NRMs necessary for those uses are established in subsequent proceedings by DEA. Those proceedings, which establish quotas pursuant to 21 U.S.C. 826, and grant permits to import pursuant to 21 CFR part 1312, are not part of this proceeding. Moreover, there is nothing in the legislative history of the statute that supports any intention to limit the number of importers under the statute. *See Johnson Matthey, Inc., Grant of Registration to Import Schedule II Controlled Substances*, 67 FR 39041, 39043 (DEA 2002). Accordingly, the Deputy Administrator adopts the ALJ's ruling on this issue, and finds that Chattem's proposed importation of raw opium and CPS is ''necessary to provide for medical, scientific, or other legitimate purposes.''

B. The Adjudication

Longstanding Federal policy 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. Therefore, NRMs 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.

At the time of the hearing, Noramco and Mallinckrodt were the only companies registered with DEA as importers of NRMs. By order of May 22, 2002, DEA granted a conditional registration to Johnson Matthey, Inc., to import NRMs. *See Johnson Matthey,*

[2] In Chattem's Proposed Findings of Fact and Conclusions of Law, Chattem contended that the ALJ did not decide Noramco's motion to substitute Ortho McNeil as a party to these proceedings. Chattem opposed the motion, contending that Noramco should not be permitted to be a party to the proceeding, since Noramco, at the time of the hearing, was not a corporation, but was a division of Ortho-McNeil, and Noramco's DEA registration as an importer was issued to ''Noramco, Inc., a division of Ortho McNeil, Inc.'' The Deputy Administrator hereby grants Noramco's motion to substitute.

supra. By order of January 29, 2003, DEA granted a registration to Penick to import NRMs. *See Penick, supra.* At the time of the hearing, Chattem had to purchase NRMs from Mallinckrodt or Noramco in order to manufacture APIs. After Chattem applied to DEA to be registered to import NRMs, Noramco, Mallinckrodt, Penick and the Government opposed Chattem's application and asked for a hearing.

At present, Mallinckrodt, Noramco, Penick, Johnson Matthey and Chattem are also registered with DEA as bulk manufacturers of morphine, codeine and oxycodone, all of which are products made from NRMs. Chattem is also registered with DEA as an importer of controlled substances other than NRMs. In 2002 DEA granted registrations to three additional companies for the bulk manufacture of controlled substances made from NRMs. See Rhodes Technologies, 67 FR 36917 (DEA 2002), *Houba, Inc.*, 67 FR 40752 (DEA 2002) and *Cedarburg Pharmaceuticals, L.L.C.*, 67 FR 42058–02 (DEA 2002). Notably, these registrations were granted *after* the Government took the position in this proceeding that registering Chattem as an importer of NRMs was not in the public interest.

Any company that wishes to import NRMs must comply with the ''80–20 rule,'' which requires that 80 percent of the NRMs imported into the United States have as their original source Turkey or India. The remaining 20 percent must come from Yugoslavia, France, Poland, Hungary, or Australia. 21 CFR 1312.13(f). At the hearing, Frank Sapienza, then Chief of DEA's Drug and Chemical Evaluation Section in DEA's Office of Diversion Control, testified that the purpose of the rule is to limit diversion of raw materials by avoiding a proliferation of countries producing NRMs. He also testified that DEA estimates that ten to thirty percent of India's poppy crop is diverted.

Pursuant to 21 U.S.C. 958(a) and 823(a), DEA is required to register Chattem as an importer 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 determining the public interest, DEA must consider the factors enumerated at U.S.C. 958 and 823(a)(1)–(6) and 21 CFR 1301.34(b)(1)–(7), many of which are identical. Accordingly, the Deputy Administrator will first consider United States obligations under international treaties, then each of the factors delineated in 21 U.S.C. 823(a) and 21 CFR 1301.34(b)(1)–(7), as follows.

1. Treaty Obligations

The Objectors did not adduce sufficient evidence at the hearing that the importation of NRMs by Chattem would violate or be inconsistent with United States obligations under international treaties, conventions or protocols. The United States is a party to a number of international drug control treaties, including the United Nations Single Convention on Narcotic Drugs of 1961 (the Single Convention). Under the Single Convention, 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.

Mr. Sapienza testified at the hearing about DEA's obligations under the Single Convention and other treaties. He testified that the United States is the world's largest importer of NRMs, and the commentary on the Single Convention states that ''it may be advisable or even essential to keep to a minimum the number of licensees of manufacturers and international traders (importers as well as exporters) or of the state enterprises engaged in these activities.'' *Commentary on the Single Convention on Narcotic Drugs*, 1961, United Nations, New York, 1973, p. 264. The Deputy Administrator agrees that the Single Convention provides important guidance on the registration of importers of NRMs and manufacturers of bulk narcotics. The Deputy Administrator finds that the evidence did not show that it would be ''advisable'' or ''essential'' to deny Chattem's application for registration. Moreover, as set forth more fully below, the Deputy Administrator finds that registration of Chattem would not likely cause significant increased diversion. Accordingly, the Deputy Administrator finds that registering Chattem as an importer of NRMs at this time would violate or be inconsistent with the Single Convention or other treaties.

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 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. *Diversion*

There is no dispute in the record that Chattem maintains adequate security at its manufacturing plant. David Blum, Ph.D., Chattem's Vice President of Operations, testified extensively about Chattem's internal security measures. The DEA Diversion Investigator (DI) who conducted the investigation of Chattem's application testified favorably about Chattem's security. Moreover, Mr. Sapienza testified that there were no documented cases of diversion of NRMs imported into the United States, and no significant diversion at the bulk manufacturing level. The Deputy Administrator therefore finds Chattem has met its burden of proof in showing that there is no significant risk of diversion of imported NRMs or other controlled substances from, or in transit to, Chattem's facilities.

The Government alleged that the addition of Chattem as an importer of NRMs could increase the diversion of the Schedule II controlled substances in the United States, ''downstream'' at the retail level. Mr. Sapienza testified that the abuse and diversion of prescription narcotics at the retail level, especially oxycodone, hydrocodone and OxyContin, a time-released brand of oxycodone, appears to be increasing at an alarming rate. The Government argued that registering another importer could lead to increase diversion at the retail level because of the potential of increased importation, increased manufacturing of bulk narcotic APIs, an increased number of products, increased inventories and greater availability of narcotic medication.

The Deputy Administrator finds that the Government's evidence showed that the diversion of Schedule II narcotics at the retail level has greatly increased in recent years, and is an extremely serious problem. The evidence also shows that DEA continued to register bulk manufacturers of oxycodone; hydrocodone and other narcotics made from NRMs after the Government took a position against granting Chattem's application as an importer. The Objectors offered no explanation of this fact, and there is little evidence in the record that Chattem's registration as an importer would have any greater effect on diversion downstream than DEA's continued registration of bulk manufacturers. Moreover, 21 U.S.C. 823(a)(1) does not differentiate between importer and bulk manufacturer registrations in its discussion of the possibility of limiting such registrations in order to avoid diversion. Also, the Government's evidence showed that new registrations of *both* bulk manufacturers of Schedule II controlled substances and importers of NRMs were

a potential source of increased diversion downstream, and that the efforts to control diversion of controlled substances made from NRMs ''must start at the source of the bulk material (importer and manufacturer) and its products (dosage form manufacturers).'' There was also evidence adduced that importer registrants do not have a free hand; the Government has the ability to restrict imports of NRMs with respect to the number of countries and proportions allowed from each. The Deputy Administrator also notes that DEA has the authority to restrict the issuance of import permits for NRMs if it finds that such importation is not necessary to provide for medical, scientific, or other legitimate purposes. 21 CFR 1312.13.

Also, based upon the testimony of Julie L. Tisinger, a DEA Drug Science Officer with DEA's Drug and Chemical Evaluation Section, it does not appear that registering Chattem as an additional importer would necessarily increase the demand or availability of Schedule II narcotics at the retail level. As Ms. Tisinger testified, DEA establishes manufacturing and procurement quotas each year for Schedule II controlled substances in order to avoid the overproduction of these substances, for the purpose of reducing the risk of diversion to illicit traffic. Such quotas are determined by information obtained from manufacturers, which includes past and present sales, anticipated need and existing inventories. Thus the evidence showed that the demand for retail products is the major factor that results in increases in the bulk manufacturing and importation of NRMs. It therefore appears unlikely that granting Chattem's application for a registration to import NRMs would be a significant cause of increased diversion at the retail level. Moreover, Chattem is already registered with DEA as a bulk manufacturer of products made from NRMs. Therefore Chattem's need for NRMs is already a factor in determining DEA quotas. Chattem's registration as an importer would not change that, but would simply permit Chattem to purchase NRMs directly from foreign suppliers rather than from Mallinckrodt and other companies already registered with DEA as importers of NRMs. Accordingly, while the Deputy Administrator realizes that diversion of narcotics at the retail level is an extremely serious problem, the Deputy Administrator finds that there is no solid evidence in the record that granting Chattem a registration to import NRMs would have the potential to increase the demand or availability of narcotics medications, or cause a corresponding increase in diversion at the retail level.

The Government also argued that registering Chattem would make it more difficult for DEA to control diversion inside the United States because DEA conducts more inspections of importers and manufacturers than of physicians and pharmacies. The Deputy Administrator finds, however, that the evidence did not show that the addition of one more NRM importer would cause any significant strain on DEA resources, or result in increased diversion at the retail level. Chattem is already registered as a bulk manufacturer of controlled substances, which will require additional inspections, and there was no evidence that an inspection of a manufacturer/importer is more consuming of DEA resources than that of a manufacturer that does not import NRMs. Also, DEA's continued registration of bulk manufacturers after its opposition to Chattem's application shows that DEA has the capacity to handle an increased number of inspections of manufacturers and importers.

The Government also argued that efforts to control diversion must involve the availability of controlled substances at their points of diversion, which includes diversion at the international level. The issue of whether DEA should also consider the possibility of foreign diversion in granting registrations to import NRMs has been discussed in prior cases. In *Johnson Matthey, supra*, the Deputy Administrator found that DEA was not required to consider foreign diversion in determining whether to grant a registration for the import of controlled substances. The appellate court in *Noramco, supra*, agreed with this position, basing its opinion on the legislative history of 21 U.S.C. 823(a). *Noramco of Delaware Inc.* v. *Drug Enforcement Administration*, 375 F.3d 1148 (DC Cir. 2004) at 1155–56. The Government argued, however, that the possibility of foreign diversion should be considered in this matter, as the United States is a world leader in promoting international and domestic control of narcotics and other controlled substances.

The evidence showed that the Single Convention urges all participants to assist in limiting the production, manufacture, importation, exportation, distribution and use of drugs exclusively to legitimate medical and other purposes. Moreover, DEA's Mission Statement discusses DEA's responsibility to coordinate and cooperate with foreign governments in programs designed to reduce the availability of illicit drugs subject to abuse on the United States market.

The Deputy Administrator agrees that DEA has already assumed a major role in controlling the diversion of controlled substances around the world. Accordingly, the Deputy Administrator finds the failure in prior cases to give any consideration to international diversion was too narrow an interpretation of the 21 U.S.C. 823(a), which permits the Deputy Administrator to consider any additional matters relevant to the public health and safety. The Deputy Administrator therefore finds that DEA should consider international diversion in the granting of NRM import registrations. Based upon the legislative history of 21 U.S.C. 823(a), however, as set forth in *Noramco*, such consideration should be limited to evidence of the contribution of foreign diversion to diversion in the United States.

In this matter, however, the Deputy Administrator finds that the Objectors adduced insufficient evidence that foreign diversion was likely to occur if Chattem were registered as an importer of NRMs, and no evidence of the effect of such diversion, if it were to occur, on the diversion of narcotics in the United States. The Deputy Administrator finds that there is no question that a certain percentage of the opium produced in India is commonly diverted at the grower level. Several witnesses, including an official of the United States Department of State, testified at the hearing that the addition of another importer might cause an increase in production and an oversupply of opium in India, causing further diversion of Indian opium. There was no hard evidence, however, that the addition of one importer of NRMs would cause any significant increase in the amount of diversion of opium in India, particularly when considered in light of DEA's continued registrations of bulk manufacturers of APIs. The evidence showed that if the registration of Chattem as an importer of NRMs would cause increased diversion of opium in India, such diversion would also be caused by DEA's continued registration of bulk manufacturers of narcotics. While the Government argued that NRM importer registrations have a different effect on diversion in India than the registration of bulk manufacturers, the Government offered no solid evidence in support of this proposition, or the proposition that such diversion would cause increased diversion of controlled substances in the United States. Accordingly, while the Deputy Administrator agrees that the diversion

of opium in India is a serious and continuing problem, the Deputy Administrator finds no substantial evidence in the record that Chattem's registration as an importer would result in a significant increase in foreign diversion of NRMs, or that such diversion, if it were to occur, would significantly increase diversion of controlled substances in this country.

The Deputy Administrator therefore finds that Chattem has met its burden of proof in showing that its registration as an importer of NRMs will not significantly interfere with the maintenance of effective controls against diversion. Moreover, it would be inequitable to deny an importer registration to Chattem while continuing to register bulk manufacturers of narcotics made from NRMs. The Deputy Administrator therefore finds that this factor favors the registration of Chattem as an importer of NRMs.

b. *Adequate Competition and Adequate Supply*

The ALJ Opinion included consideration of the issues of whether there is adequate competition in the NRM processing market, and whether the current importers can provide an adequate supply. She did so, however, only because she found that Chattem had not met its burden of proof in showing that diversion would not occur as a result of its registration. In *Johnson Matthey*, the Deputy Administrator found that in determining whether to register an importer of NRMs, DEA need not consider the issue of adequate competition or the adequacy of supply unless DEA finds that diversion cannot be effectively controlled. The court in *Noramco* agreed that this determination was a sound interpretation of DEA policy. Unlike *Johnson Matthey*, however, in *Penick*, a later case involving a challenge to an application for registration as an importer of NRMs, the Deputy Administrator did consider whether there was adequate competition in the NRM processing market even though the Deputy Administrator also found that the registration of Penick was unlikely to result in diversion of controlled substances. The *Noramco* court, however, which issued its opinion after the *Penick* Final Order, approved the application of the DEA policy, as applied in *Johnson Matthey*, of not considering the adequacy of competition in both the registration of bulk manufacturers of Schedule I and II controlled substances and registration of NRM importers, if the Deputy Administrator finds that there are sufficient controls against diversion. *Noramco* at 1153. The Deputy Administrator will therefore follow the policy applied in *Johnson Matthey* and approved by the appellate court in *Noramco.* Accordingly, in light of the Deputy Administrator's finding above concerning the lack of evidence of potential diversion, the Deputy Administrator will not consider the adequacy of competition or supply in this matter.

3. Compliance With Applicable State and Local Law

There is no significant evidence that Chattem has failed to comply with applicable State and local law. The evidence showed that on two occasions in the past, Chattem destroyed controlled substance in violation of DEA policy. Chattem's actions, however, were based on the advice of a Diversion Investigator in a DEA field office, and none of the Objectors adduced evidence to the contrary. Moreover, Dr. Blum testified that Chattem intended to fully comply with all DEA laws and regulations. The evidence also showed that the Food and Drug Administration (FDA) issued a warning letter to Chattem in 2000 revealing various deviations from Current Good Manufacturing Practices. Dr. Blum testified that the deficiencies were corrected and the matter resolved. Chattem also introduced into evidence FDA warning letters to Ortho-McNeil Pharmaceuticals, (Noramco's owner at the time of the hearing), and Mallinckrodt. The Deputy Administrator therefore finds that this factor weighs in favor of granting Chattem's application.

4. Promotion of Technical Advances in the Art of Manufacturing These Substances and the Development of New Substances

Dr. Blum testified that Chattem has produced advances in the art of manufacturing those controlled substances that it is already registered to produce. Dr. Blum also testified that Chattem intends to attempt to develop a process to produce thebaine from PSC if registered as an importer. There was little evidence, however, that Chattem has achieved any noteworthy success in technical advances in the manufacturing of controlled substances, or in the development of new substances or patents. Accordingly, the Deputy Administrator finds that this factor weighs against granting Chattem's application.

5. Prior Conviction Record of Applicant Under Federal And State Laws Relating to the Manufacture, Distribution, or Dispensing of Such Substances

It is undisputed that neither Chattem nor any of its officers, agents, or key employees has been convicted of any Federal or State law relating to the manufacture, distribution, or dispensing of controlled substances. The Deputy Administrator therefore concludes that this factor weighs in favor of granting Chattem's application.

6. Past Experience in the Manufacture of Controlled Substances and the Existence in the Establishment of Effective Controls Against Diversion

The evidence in the record showed that Chattem maintains effective controls against diversion, as discussed above. The record also showed that Chattem has experience in manufacturing controlled substances other than narcotics produced from NRMs. Chattem has no experience, however, in processing NRMs. Chattem introduced credible evidence, however, that the processing of NRMs is not complicated, and that Chattem has sufficient facilities to carry out the process. Dr. Frank Stermitz, Centennial Professor Emeritus of chemistry at Colorado State University, testified that the fundamental procedures for extracting and isolating alkaloids from NRMs do not require sophisticated technology or specialized equipment. Dr. Stermitz further testified that Chattem has experience in handling alkaloid-like materials that could be directly applicable to the processing of opium alkaloids. The ALJ gave little weight to that part of Dr. Stermitz's testimony concerning Chattem's plans for large scale production of APIs. The ALJ did not, however, comment negatively upon Dr. Stermitz's additional testimony concerning the process for the extraction of alkaloids from NRMs. Some of the Objectors introduced evidence that processing NRMs was not a simple process, and that Chattem was unlikely to possess the necessary technology to efficiently process NRMs. Similar to the Deputy Administrator's finding in *Johnson Matthey*, however, the Deputy Administrator finds that the record here showed by a preponderance of the evidence that the extraction of alkaloids from NRMs is not a new or complex process. Moreover, DEA has already granted a bulk manufacturing registration to Chattem for the manufacture of APIs from NRMs, and at the time of the hearing DEA had already issued a procurement quota to Chattem

for the purchase of PSC. It seems improbable that DEA would have issued the registration and quota if it had concerns about Chattem's technology for processing NRMs. The Deputy Administrator therefore finds that the evidence showed that Chattem possesses sufficient technology to process NRMs with efficiency. Accordingly, the Deputy Administrator concludes that this factor weighs in favor of granting Chattem's application.

7. Such Other Factors as May Be Relevant to and Consistent With the Public Health And Safety

The Deputy Administrator agrees with the ALJ's finding that there are no factors that might be relevant to and consistent with the public health and safety other than those discussed above.

C. Exceptions

All of the Objectors filed exceptions to the ALJ Opinion. Chattem responded to those exceptions. Having considered the record in its entirety, including the parties' exceptions and responses, the Deputy Administrator finds no merit in any of the exceptions, most of which concerned matters that were addressed at length at the hearing. The exceptions were extensive and are part of the record. Only one of the exceptions merits further discussion, and the remainder will not be restated herein.

In its exceptions, Mallinckrodt argued that conditions should be placed upon Chattem's registration, requiring Chattem to provide DEA with plans for a new facility capable of processing both opium and PSC and providing DEA with plans and a time table for upgrading and expanding its controlled substances facilities and equipment to meet Chattem's needs. The Deputy Administrator finds no need for such conditions. The evidence showed that while Chattem has potential plans to build a larger facility if warranted by its future sales, it currently has sufficient facilities to process both opium and PSC.

IV. Conclusion

Based upon the foregoing, the Deputy Administrator finds that Chattem has met its burden of proof to show that it is in the public interest, as defined by 21 U.S.C. 823(a) and 21 CFR 1301.34(b), to grant its application to be registered as an importer of NRMs. This decision is effective March 29, 2006.

Dated: February 17, 2006.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E6–2696 Filed 2–24–06; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Proposed Extension of Information Collection; Comment Request; ERISA Summary Annual Report

AGENCY: Employee Benefits Security Administration, Department of Labor.

ACTION: Notice.

SUMMARY: The Department of Labor (the Department), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA 95). This program helps to ensure that the data the Department gathers can be provided in the desired format, the reporting burden (time and financial resources) is minimized, the public clearly understands the Department's collection instruments, and the Department can accurately assess the impact of collection requirements on respondents. Currently, the Employee Benefits Security Administration (EBSA) is soliciting comments concerning an extension of the information collections in the regulation implementing the requirement under the Employee Retirement Income Security Act of 1974 (ERISA) that administrators of employee benefit plans annually furnish participants and certain beneficiaries a statement that fairly summarizes the plan's latest annual report. A copy of the information collection request (ICR) may be obtained by contacting the office listed in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office shown in the **ADDRESSES** section on or before April 28, 2006.

ADDRESSES: Direct all written comments regarding the information collection request and burden estimates to Susan G. Lahne, Office of Policy and Research, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410, FAX (202) 219–4333. These are not toll-free numbers. Comments may also be submitted electronically to the following Internet e-mail address: *ebsa.opr@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 104(b)(3) of ERISA and the regulation published at 29 CFR 2520.104b–10 require, with certain exceptions, that administrators of employee benefit plans furnish annually to each participant and certain beneficiaries a summary annual report (SAR) meeting the requirements of the statute and regulation. The regulation prescribes the content and format of the SAR and the timing of its delivery. The SAR provides current information about the plan and assists those who receive it in understanding the plan's current financial operation and condition. It also explains participants' and beneficiaries' rights to receive further information on these issues.

EBSA previously submitted the information collection provisions in the regulation at 29 CFR 2520.104b–10 to the Office of Management and Budget (OMB) for review in an information collection request (ICR). OMB approved the ICR under OMB Control No. 1210–0040. The ICR approval is scheduled to expire on May 31, 2006.

II. Desired Focus of Comments

The Department is particularly interested in comments that:

- 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;
- 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;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Evaluate whether and to what extent the proposed collection of information minimizes 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 forms of information technology, *e.g.*, by permitting electronic submissions of responses.

III. Current Action

This notice requests comments on an extension of the information collections in the ERISA Summary Annual Report regulation. After considering comments received in response to this notice, the Department intends to submit the ICR to OMB for continuing approval. No change to the existing ICR is being proposed or made at this time. A