sentence add the word ''test'' before the word ''frame''.
■ d. Redesignate paragraphs (a)(6)(v) through (a)(6)(ix) as paragraphs (a)(6)(vi) through (a)(6)(x) respectively; redesignate the fourth through the last sentence of paragraph (a)6)(iv) as paragraph (a)(6)(v); and add the heading ''*Burner inlet lines.*'' to newly designated paragraph (a)(6)(v).
■ e. In redesignated paragraph (a)(6)(vi) before the word ''*Frame*'' in the heading of the paragraph add the word ''*Burner*''.
■ f. In redesignated paragraph (a)(6)(vii) in footnote 1 remove the phrase ''3 inch ID by inch OD'' and add in its place the phrase ''0.25 inch ID by 0.4 inch OD''.
■ g. In redesignated paragraph (a)(6)(ix), second sentence, remove the number ''70'' and in its place add ''140 ± 5''; after the number ''20'' add ''± 1''; after the word ''Figure'' remove the number ''8'' and add the number ''7'' in its place.
■ h. In paragraph (b)(1)(ii), the last sentence, remove ''20 ± .5'' and in its place add ''20 ± 1''.
■ i. In paragraph (d)(1), first sentence, before ''0.5 m/s'' add the words ''no more than''.
■ j. In paragraph (d)(2), third sentence, remove the word ''bed'' and add in its place the word ''test''; remove the fourth sentence and add in its place ''Carefully center the foundation on top of the test frame to eliminate any gaps between the bottom periphery of the foundation and the inside edges of the test frame. If the mattress is to be tested alone, place it similarly. A mattress tested with its foundation should be centered longitudinally and laterally on the foundation.''.
■ k. In paragraph (e) remove the number ''(ix)'' and add in its place the number ''(x)''.
■ l. In paragraph (f) move the third sentence so that it becomes the first sentence of the paragraph.
■ m. In paragraph (h)(1)(iv) add at the end of the first sentence the words ''or another dimension that meets the requirements for a specific sample''; remove the last sentence of the paragraph.
■ n. In paragraph (h)(2)(i) remove the last sentence and add it in its place the words ''Use a sufficient length of duct tape (platen to mattress top) to assure that the platen stays firmly against the surfaces of the mattress.''.
■ o. In paragraph (h)(2)(iv) remove the first sentence and add in its place the sentence ''Make the horizontal burner parallel to the top of the platen (within 3 mm (⅛ inch) over the burner tube length); when properly parallel, it should not be possible to insert the 3 mm flat stock under either burner end by bending the copper tube section appropriately.''.
■ p. In paragraph (h)(2)(viii), first sentence, remove the word ''its'' and add in its place the words ''the vertical burner''; move the reference to footnote 9 to the end of the second to last sentence in the paragraph.
■ q. In paragraph (i)(2)(i) in the second to last sentence remove the abbreviation ''ca.'' and add in its place the word ''approximately''.
■ 3. Section 1633.12 is amended as follows:
■ a. In paragraph (a)(6)(iii) before ''; and'' add the sentence ''Such foundation(s) shall be clearly identified by a simple and distinct name and/or number on the mattress label''.
■ b. In paragraph (d) after the word ''paragraphs'' remove the phrase ''(a)(7)(i) and (a)(7)(ii), and (a)(7)(iii)'' and add in their place the phrase ''(a)(6)(i) through (iii) and (a)(7)(i) through (iii)''.

Dated: January 30, 2008.

Todd Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. E8–2027 Filed 2–5–08; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1312

[Docket No. DEA–282F]

RIN 1117–AB03

Authorized Sources of Narcotic Raw Materials

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is amending the list of non-traditional countries authorized to export narcotic raw materials (NRM) to the United States by removing Yugoslavia and adding Spain. This rule provides DEA registered importers with another potential source from which to purchase NRM that are used in the production of controlled substances for medical purposes in the United States.

DATES: *Effective Date:* This rule is effective March 7, 2008.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

DEA enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801, *et seq.*), as amended. DEA regulations implementing these statutes are published in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to 1316. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial purposes and to deter the diversion of controlled substances to illegal purposes. The CSA and its implementing regulations are consistent with United States treaty obligations that, among other things, address the production, import, and export of controlled substances.

Controlled Substances

Controlled substances are drugs that have a potential for abuse and psychological and physical dependence, including opiates, stimulants, depressants, hallucinogens, anabolic steroids, and drugs that are immediate precursors of these classes of substances. DEA lists controlled substances in 21 CFR Part 1308. The substances are divided into five schedules. Schedule I substances have a high potential for abuse and have no accepted medical use in treatment in the United States. These substances may only be used for research, chemical analysis, or manufacture of other drugs. Substances listed in schedules II—V have accepted medical uses but also have potential for abuse and psychological and physical dependence. Narcotic raw materials (opium, poppy straw, and concentrate of poppy straw (CPS)) are in schedule II and are the materials from which morphine, codeine, thebaine and oripavine are extracted for purposes of manufacturing a number of schedule II and III controlled substances.

Sources of Narcotic Raw Materials

In May 1979, the United Nations' Economic and Social Council (ECOSOC) adopted Resolution 471, which called on importing countries such as the United States to support traditional suppliers of NRM and to limit imports from non-traditional supplying countries. The resolution, which was reaffirmed by ECOSOC in 1981, was

adopted to limit overproduction of NRM, to restore a balance between supply and demand, and to prevent diversion to illicit channels. The United States, based on long-standing policy, does not cultivate or produce NRM, but relies solely on opium, poppy straw, and CPS produced in other countries for the NRM necessary to meet the legitimate medical needs of the United States. In response to Resolution 471, on August 18, 1981, DEA published a final rule specifying certain source countries of NRM (46 FR 41775); the rule is frequently referred to as the 80/20 rule. Under the final rule, currently codified at 21 CFR 1312.13(f) and (g), NRM can be imported from only seven countries. Traditional suppliers India and Turkey must be the source of at least 80 percent of the United States' requirement for NRM. Five non-traditional supplier countries—France, Poland, Hungary, Australia, and Yugoslavia—may be the source of not more than 20 percent. The 80/20 rule is calculated based on the amount of morphine alkaloid contained in the NRM. The United States continues to reaffirm its support of the original resolution by supporting similar resolutions each year at the Commission on Narcotic Drugs.

Just as with DEA's 1979 **Federal Register** publication first proposing the 80/20 rule (44 FR 33695), it is important to recite here some of the central principles of Resolution 471, which remain crucial today:

> Noting that in recent years there has been considerable stepping up of morphine producing capacity for export, leading to a situation of substantial overproduction of opiates,
>
> * * * * *
>
> Recognizing that it is essential to bring about a proper balance between the global supply and demand,
>
> Taking note of the continued reliance placed by the world community on countries constituting the traditional sources of supply for its medical needs of opiate raw materials and the positive response of these countries in meeting the world requirements and their contribution in the maintenance of effective control systems;
>
> Bearing in mind that the treaties which establish this system are based on the concept that the number of producers of narcotic materials for export should be limited in order to facilitate effective control;
>
> * * *

In view of these principles underlying Resolution 471, DEA stated in proposing the 80/20 rule in 1979:

> The United States is a significant importer of narcotic raw materials. Its manufacturers account for one-third of the world morphine manufacturing capacity, most of which is consumed within the United States in the form of codeine.[1] The worldwide overproduction of narcotic raw materials and [Resolution 471] make it necessary for the United States to reevaluate past and present narcotic policies.
>
> Historically, the United States has relied exclusively upon imports of opium gum to manufacture our narcotic medical supplies instead of cultivating opium poppies in the United States. The rationale behind this 57-year-old policy, which foregoes [sic] U.S. self-sufficiency, was to set an example to the world community to refrain from overproduction and to limit the number of opium-producing nations to a minimum.
>
> [44 FR 33696, June 12, 1979]

The foregoing principles remain central to United States drug control policy and this final rule amending the 80/20 rule.

Of the countries included in the 80/20 rule, India is the only country that cultivates poppies for production of opium. All other exporting countries use the CPS method of NRM production, a method that allows the plant to go to seed; portions of the plant are then processed into a concentrate. It is generally believed that CPS is less divertible than opium. CPS may be rich in morphine (CPS–M), rich in thebaine (CPS–T), or rich in oripavine (CPS–O). The United States imports the majority of its CPS–M from Turkey, with Australia supplying the vast majority of the balance. The vast majority of CPS–T and all CPS–O are imported from Australia.

The 80/20 rule was established based on traditional import amounts and on the United Nations resolution calling on member nations to support traditional sources that have been reliable suppliers and to take measures that curtail diversion. The United States allowed a limited number of non-traditional suppliers to have access to the United States market based on past commercial relationships and on the desirability of preserving alternative sources. This approach was consistent with the United Nations Resolution because it supported India and Turkey and ensured an adequate and uninterrupted supply of NRM while limiting the number of supplying countries. Over the last ten years, pursuant to the 80/20 rule, DEA registered importers of NRM have imported 90 percent of United States NRM requirements from traditional suppliers India and Turkey. DEA continues its support of the intent of the 80/20 rule.

[1] Today, the United States remains a significant importer of narcotic raw material. Its manufacturers currently account for one-fourth of the world morphine manufacturing capacity, with roughly two-thirds being utilized for the production of codeine, which is consumed as either codeine or hydrocodone.

On June 6, 2005, the Kingdom of Spain (hereinafter referred to as Spain) petitioned DEA seeking to be added to the list of non-traditional suppliers. Spain stated four reasons that granting its petition would be consistent with United States interests:

- The change would be consistent with the 80/20 rule because it maintains India and Turkey as the two traditional supplier countries, that is, Spain does not seek to be added to the list of traditional suppliers.
- The change would ensure adequate supplies of NRM.
- The change would not result in diversion because Spain maintains strict control and oversight over the cultivation and distribution of NRM.
- The change would allow DEA to monitor diversion and maintain cost-effective supplies.

In its petition, Spain explained that in the early 1970s, Spanish pharmaceutical firms sought authorization to cultivate opium poppies to produce NRM. In 1973, the Government of Spain authorized a single firm, Alcaliber, S.A., to cultivate, harvest, store, and prepare extracts from the opium poppy. Spain is now the fifth largest cultivator of opium poppies; Spain is the fourth largest producer of CPS and the third largest exporter of CPS–M.[2] Spain has ratified international agreements to control production and commerce in opium products. As stated in its petition, Spain has implemented a comprehensive regulatory regime for controlling the cultivation, production, and export of NRM in accordance with international treaty requirements. The petition stated that this control ensures that NRM produced in Spain are not diverted to illicit uses.

After review of the petition, DEA published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** on October 4, 2006 (71 FR 58569) to amend the list of non-traditional countries authorized to export NRM to the United States. Specifically, the proposed rule sought to revise the list of non-traditional suppliers by removing Yugoslavia and replacing it with Spain. At that time, DEA had determined that the successor states to Yugoslavia no longer produced NRM for export beyond Yugoslavia's prior border (e.g., Serbia and Montenegro reported exports to the Republic of Macedonia (hereinafter referred to as Macedonia) only). Therefore, DEA concluded that

[2] ''Narcotic Drugs: Estimated World Requirements for 2005—Statistics for 2003'', Tables II and XIII; International Narcotics Control Board (E/INCB/2004/2).

replacing Yugoslavia with Spain would continue to limit the number of non-traditional suppliers to the United States while ensuring the availability of an adequate number of sources of NRM for United States manufacturers. The proposed change would not otherwise affect the implementation of the 80/20 rule.

Comments Received

Following publication of the Notice of Proposed Rulemaking on October 4, 2006, DEA received a request for a 60-day extension to the comment period. On December 1, 2006, DEA extended the comment period of the proposed rule to January 3, 2007 (71 FR 69504).

During the comment period, DEA received 14 comments from 13 interested parties. Five comments were received from the following countries: Australia, Spain, Macedonia, and Turkey. One of the comments received from a foreign Government was a joint comment with a foreign control board. Three comments were received from three DEA-registered importers of NRM; one comment was received from a DEA-registered opiate manufacturer; one comment was received from a non-DEA registered firm; two comments were received from two foreign NRM manufacturers; and two comments were received from one individual. As part of the above-listed comments, DEA also received a request to extend the comment period, and four requests for a hearing.

After the comment period had ended, DEA received an additional comment from a foreign NRM manufacturer. This prompted two additional late comments, one from the foreign control board which previously commented on the NPRM and the other from the foreign government associated with that foreign control board. Specifically, both commenters sought clarification from DEA on the status of the late comment, which DEA had administratively added to the docket. The Administrative Procedure Act (APA) does not address the issue of late comments, and the United States courts generally defer to federal agencies in their handling of late comments. It is the policy of the DEA that comments not properly filed, e.g., comments postmarked after the close of a comment period, will not be considered by the agency in its deliberative process. Accordingly, the late comment from the foreign NRM manufacturer was not considered by DEA in this Final Rule. All comments received during the comment period are summarized here and discussed further below.

Comments in Support of DEA's NPRM

Four of the commenters supported the proposed rule. These commenters included the Government of Spain, a DEA registered NRM importer, one foreign NRM manufacturer, and a DEA-registered opiate manufacturer. One of the DEA registrants commented that the need to ensure an adequate number of sources of NRM for DEA-registered NRM importers is ''most keenly felt in CPS–T and CPS–O, for which the U.S. demand is rapidly growing and in which global supply sources to the U.S. are currently quite limited.''

Comments Raising Concerns to DEA's NPRM

Nine of the commenters raised various concerns regarding the NPRM. These commenters included the Government of Australia, the Government of Macedonia, and the Government of Turkey; a foreign NRM control board; two DEA-registered importers of NRM; one non-DEA-registered firm; one foreign NRM manufacturer; and one individual.

Four commenters claimed that the proposed rule would exacerbate current global oversupplies of NRM and therefore disrupt the balance between the supply of and demand for NRM. Three commenters claimed that the proposed rule was not consistent with the intent of the 80/20 rule or international resolutions. Three commenters claimed that the proposed rule was not necessary to assist the United States in maintaining cost effective supplies of NRM. Three commenters questioned DEA's decision to replace Yugoslavia with Spain.

The following additional concerns were raised. One commenter believed that the addition of Spain to the list of non-traditional NRM producing countries would lead to a proliferation of NRM-producing countries. The commenter, however, did not provide further information as to how this rulemaking would specifically lead to a proliferation of NRM-producing countries. Additionally, one commenter claimed that Spain has diversion occurring within its borders and that it could not be proven that the addition of Spain to the list of non-traditional countries would not lead to an increase in diversion within Spain. While the commenter provided a general statement regarding the diversion of controlled substances, the commenter did not provide any specific evidence regarding the diversion of narcotic raw material specifically cultivated for lawful purposes in Spain. Due to the lack of substantiation for the claims discussed above, these comments are not addressed further in this rulemaking.

Request for Hearing

Four commenters requested that DEA hold an administrative hearing in this matter. Two of these commenters requested a hearing prior to the issuance of the final rule. One of these commenters stated that a hearing was appropriate ''given the gravity and complexity of the issues involved.'' The other commenter stated that a hearing would ''provide interested parties with the fullest opportunity to make their views known and have their positions considered.'' These commenters did not proffer any specific information beyond that submitted in the written comments, however, that would be brought to light if their requests for a hearing were granted. DEA has determined that an oral hearing prior to the issuance of this rule is unnecessary. The amendment of the 80/20 rule to substitute one non-traditional country for another that no longer exists in the form it did at the time of the promulgation of the original rule does not represent a major change in DEA policy or procedure. Moreover, DEA has carefully considered all of the comments received in connection with the proposal, and finds that the comments fully set forth the issues relevant to this rulemaking. Based on information provided in the comments, information provided in technical reports by the International Narcotics Control Board (INCB), and information provided by U.S. importers of NRM pursuant to DEA regulations, DEA has been able fully to address the relevant issues set forth in the comments and has determined that conducting a hearing would not materially add to the administrative record. DEA has concluded, therefore, that such a hearing would be unnecessary.

Two other commenters requested a hearing following the issuance of the final rule, if it is issued. Such a request does not conform procedurally with traditional rulemaking procedures under the APA, under which—if an agency holds a hearing in connection with a proposed rule—it is held prior to the issuance of the final rule. Moreover, neither the CSA nor DEA regulations provide for an administrative hearing to ''appeal'' the promulgation of a final rule. Pursuant to 21 U.S.C. 877, exclusive jurisdiction for appeals of DEA final decisions such as this rule rests with the United States Courts of Appeals. Accordingly, the requests for a hearing if the final rule is issued are denied.

Other Comments Received

One of the commenters wrote that if the proposal sought to change the method by which the 80/20 rule was calculated, then the commenter would object to the proposed rule. As noted previously, the 80/20 rule is calculated based on the amount of morphine alkaloid contained in the NRM. Since DEA's proposed rule and this rulemaking do not affect how the 80/20 rule is calculated, this matter is not addressed further in this rulemaking.

One commenter submitted two comments. One of these comments stated, ''So we are deciding who to allow to do the exporting of substances that are used to make heroin? We allow this? And then kick down the doors of terminally ill patients who smoke marijuana just to ease their pain. * * *'' The other comment promoted the use of hallucinogens. NRM imported into the United States pursuant to this rule are used to make legitimate medicines that are used to treat pain, not to manufacture heroin. Heroin production and the use of marijuana and hallucinogens are not the subject of this rulemaking; these matters are therefore not addressed further in this rulemaking.

Support for DEA's NPRM

Adequate Supply of NRM

Three commenters addressed the need to ensure adequate supplies of NRM for United States markets. One commenter noted that the need to ensure an adequate number of sources of NRM for DEA registered NRM importers was ''most keenly felt in CPS–T and CPS–O, for which the U.S. demand is rapidly growing and in which global supply sources to the U.S. are currently quite limited.''

DEA Response: DEA agrees that United States sources of NRM are limited based on data it collects quarterly from DEA registered importers pursuant to 21 CFR 1304.31. The data collected in these reports include the relative amounts of morphine, codeine, thebaine and oripavine contained in each individual NRM import to the United States as reported by each of the five DEA registered NRM importers. In response to this comment, DEA conducted an analysis of the source of each of the primary alkaloids available in current NRM: morphine, thebaine and oripavine. DEA notes that, in 2006, imports of NRM had as their source, four of the seven countries authorized to export NRM to the United States, specifically India, Turkey, Australia and France. United States importers have not imported NRM from Poland or Yugoslavia since at least 1985, and imports from Hungary were minimal in the mid to late 1990s and have ceased altogether since 2002. No imports from Poland, Yugoslavia, or Hungary are anticipated in 2007. Since NRM contain a mixture of these alkaloids, DEA's review of the NRM import situation (below) is expressed in terms of the amount of morphine, thebaine, and oripavine contained in imported NRM.

Morphine: Morphine is the principal alkaloid in Indian opium and Turkish CPS–M and has historically been the principal alkaloid extracted from NRM in the United States. Morphine continues to be utilized in the United States for the manufacture of morphine-based pharmaceutical products; the manufacture of codeine, which is utilized to manufacture codeine-based pharmaceutical preparations and hydrocodone; and the manufacture of hydromorphone. Based on an analysis of information received for 2006, imports of NRM totaled 124,000 kg of morphine (124.0 metric tons (MT)), having the following countries as its source: Turkey (59.9 MT morphine; 48.3 percent), India (43.9 MT morphine; 35.4 percent), and Australia (20.4 MT morphine; 16.5 percent).[3] When reviewing imports of morphine over the last 10 years (1997–2006), United States importers obtained commercial quantities of morphine from India, Turkey, and Australia, with lesser amounts obtained from France and Hungary. DEA concludes as a result that the United States has at least three geographically distinct countries from which morphine is obtained, each with large production capacity on which the United States could rely if any of those countries were to experience a hardship (i.e., crop failure, labor strife, etc.). Adding Spain would provide DEA registered importers with a fourth country from which to purchase NRM.

Thebaine: Thebaine is the principal alkaloid in CPS–T. CPS–T is available to the United States market from Australia and France. Thebaine is also present in Indian opium at approximately one sixth the level of morphine, thus the amount of thebaine obtained from India is directly related to the amount of morphine that United States importers import from India. In the United States, thebaine is utilized for the manufacture of oxycodone, a schedule II controlled substance. More recently, oxycodone has been utilized for the manufacture of oxymorphone, another schedule II controlled substance.

Oxycodone use in the United States has increased tremendously over the last 10 years. For example, the aggregate production quota for oxycodone, which represents the maximum amount that may be manufactured in the United States to meet the estimated medical, industrial, scientific, and research needs of the United States; for lawful export requirements; and the maintenance of reserve stocks, has increased over the last decade from 5,275 kg in 1997 to 49,200 kg in 2006. The large increase in oxycodone use in the United States followed the approval and marketing in 1995 of a high dose, single-entity, extended-release drug formulation known as OxyContin. Although DEA remains concerned over the diversion and abuse of OxyContin and other formulations that contain high doses of potent schedule II controlled substances, the Food and Drug Administration continues to advise DEA of double-digit growth in the oxycodone market through 2008. This provides evidence that the demand for thebaine-rich NRM that must be imported into the United States for this purpose will also continue to increase.

When the same 2006 quarterly statistical import data was reviewed for thebaine, DEA noted that 78.2 MT of thebaine was imported into the United States in 2006, having as its source the following countries: Australia (66.8 MT of thebaine; 85.4 percent), India (7.1 MT of thebaine; (9.1 percent), and France (4.1 MT of thebaine; 5.2 percent).[4] Thus, Australia was the source of 85 percent of United States thebaine requirements in 2006.[5] For comparison, in 2005, 73 percent of the 65.4 MT of thebaine imported into the United States had Australia as it source, and, in 2004, 75 percent of the 66.8 MT were imported from Australia. In 2007, United States importers have reported their plans to import 92 percent of their thebaine requirements from Australia; they planned to import the remaining 8 percent solely from India.

DEA notes that Australia has a stellar record in providing thebaine-rich NRM to the United States, with little (if any) record of diversion. DEA further notes that the United States and Australia have excellent relations in this area, and contrary to comments made by some commenters to this NPRM, DEA's proposed rule and this final rule in no

[3] Percentages may not add to 100 percent due to rounding.

[4] Ibid.

[5] As discussed previously, The 80/20 rule is calculated based on the amount of morphine alkaloid contained in the NRM. As this discussion relates to the amount of thebaine alkaloid in the NRM, not morphine, the 85 percent obtained by the United States from Australia does not violate principles of the 80/20 rule.

way suggest that Australia has ''not ensured an adequate and uninterrupted supply'' of NRM to the United States. DEA remains mindful, however, of the potential impact of a hardship (i.e., crop failure, labor strife, etc.) in Australia that could lead to a temporary lack of availability of thebaine to the United States market. In this circumstance, the United States would be required to obtain much larger volumes of NRM from either India or France in order to meet thebaine demand. Although France has demonstrated the capability of exporting up to 16 MT of thebaine in a single year to the United States, India's capacity to export thebaine, as mentioned above, is directly related to the amount of morphine that importers wish to import from India consistent with the 80/20 rule. Therefore, importing vast quantities of Indian opium to meet United States thebaine demands would be impractical because it would result in the importation into the United States of excessive amounts of morphine, which could then be the subject of diversion and abuse. Thus, the amount of thebaine that could be derived from India, consistent with United States requirements for morphine contained in Indian opium, is likely to be 6–8 MT annually. DEA concludes that the United States has limited sources from which to obtain thebaine derived from NRM. The United States relies on three countries for thebaine, but two of these countries have a limited capacity to support the increasing size of the United States' market for thebaine. DEA notes that, in 2004, the Government of Spain reported for the first time commercial production of CPS–T, so Spain would represent a fourth country from which CPS–T could be imported. As a result, this rule will provide DEA registered importers with another source from which to purchase CPS–T for the production of medicines.

Oripavine: Oripavine, a schedule II controlled substance, is the principal alkaloid found in Australian CPS–O and is a minor constituent in French CPS–T. Oripavine is becoming an increasingly important intermediate in the United States for the manufacture of buprenorphine, a schedule III controlled substance, oxymorphone, and a number of controlled and non-controlled substances referred to generally as ''opiate antagonists'' (naltrexone for example, and its derivatives). Using the same import data, DEA notes that, in 2006, 9.7 MT of oripavine was imported into the United States having Australia as its source, virtually 100 percent of the United States' oripavine requirements. In 2005, 4.1 MT were imported from Australia and in 2004, 9.4 MT were imported with roughly 86 percent imported from Australia. United States importers have reported their plans to import 100 percent of the 9.7 MT of oripavine from Australia in 2007. DEA therefore concludes that the United States has limited sources from which to obtain oripavine derived from NRM.

Objections to DEA's NPRM

Global Oversupply of Narcotic Raw Materials

The Government of Australia's primary concern regarding DEA's proposed rule is that this rule would ''exacerbate global oversupply'' of NRM. In its comment, the Government of Australia pointed to statistical data published by the INCB in its report, ''Narcotic Drugs: Estimated World Requirements for 2006—Statistics for 2004,'' which the Government of Australia characterized as demonstrating that global production of both morphine-rich and thebaine-rich NRM have been in excess of global utilization since at least 2001. As a result of overproduction, the Government of Australia argued, global supplies have increased.

The DEA-registered NRM importer stated that ''Alcaliber [the sole Spanish poppy cultivator] made a significant investment in capacity, dramatically increased production contributing significantly to global overproduction and excess stocks, and now wants access to the U.S. market to allow it to increase production further to help recover its investment.'' The importer further stated that the Notice of Proposed Rulemaking sent the message that ''If a country adds production capacity, uses it aggressively and thereby contributes to the world's build up of excess stocks, the U.S. will accommodate this behavior and reward it with access to the U.S. market. The U.S. will simply delete a smaller producer from the list.'' This commenter also stated that ''Spain was arguably the primary source of this build up in excess morphine stocks.''

Finally, the foreign opiate manufacturer stated that ''Spain's rapid expansion of its domestic industry, its aggressive approach to building export markets, its building of clearly excessive stockpiles and capacity, and supply into a market already in over-supply is not * * * broadly in accordance with the obligations under the Single Convention, or the Resolutions.''

DEA Response: DEA disagrees that Spain is the ''primary'' source of any build-up of global excesses in morphine stocks. Instead, DEA concludes that all countries that produce NRM contribute to the current global excess of NRM.

Among many of the requirements of NRM-producing countries, in accordance with the Single Convention on Narcotic Drugs, 1961, is a requirement to provide annual statistics to the INCB, including estimated amounts of NRM to be cultivated and the amount of NRM to be produced therefrom. The INCB utilizes these estimates along with other statistical data it collects, in accordance with the Single Convention, to monitor and analyze the global supply of and demand for NRM. The results of this analysis are published in a technical report series, which in 2004 was entitled, ''Narcotic Drugs: Estimated World Requirements for 2006; Statistics for 2003.'' The analysis conducted by the INCB and the statistical reports published continue to be an excellent resource for governments of consumer countries such as the United States. A review of this report series for 2004 and 2005 was conducted with relevant statistical data provided in Tables 1 and 2.

Analysis for Morphine-Rich Poppies

TABLE 1.—''GLOBAL CULTIVATION OF MORPHINE-RICH POPPIES (HECTARES) FOR LICIT PURPOSES OTHER THAN PRODUCTION OF OPIUM''

Country	2003 (ha)	2004 (ha)	2005 (ha-est.)	2006 (ha-est.)
Australia	9,811	6,644	6,700	4,900
People's Republic of China	1,250	1,000	1,300	1,200
Czech Republic	21,045	16,030	25,000	38,000
France	7,919	8,312	8,500	9,100
Hungary	2,937	7,084	14,000	12,000
Slovakia	332	326	550	.....

TABLE 1.—''GLOBAL CULTIVATION OF MORPHINE-RICH POPPIES (HECTARES) FOR LICIT PURPOSES OTHER THAN PRODUCTION OF OPIUM''—Continued

Country	2003 (ha)	2004 (ha)	2005 (ha-est.)	2006 (ha-est.)
Spain	5,732	5,986	7,002	6,002
Republic of Macedonia	51	91	1,500	1,500
Turkey	99,430	30,343	70,000	70,000
United Kingdom	1,534	1,534	1,500	.....
Total	150,041	77,350	136,052	142,702

Neither DEA, nor any commenter, identified a single instance in these reports in which the INCB raised concerns over Spain's purported role in the global excess of production and the resulting oversupply of NRM presently on hand. According to this publication, Spain was one of eleven countries that cultivated morphine-rich poppies in 2003 for licit pharmaceutical purposes (i.e. non-culinary use). Spain planted 5,732 hectares of poppies and produced roughly 4.7 percent of the world's morphine-rich poppy straw. Spain's share of world production of poppy straw increased in 2004 to 10.7 percent; the increase was attributed to both an increase in 2004 acreage sown in Spain and a large decrease in acreage sown by the primary cultivator of poppies for this purpose, Turkey. Estimates for the ''area to be cultivated'' for 2005 and 2006 suggest that Spain will be responsible for 5.1 percent of the area under cultivation and had plans to decrease its area under cultivation in 2006 to 4.2 percent.

Although Spain remains one of the five largest cultivators of morphine-rich poppies in the world, DEA concludes that Spain, like all other producer and consumer countries, contributes to what the INCB qualifies as a ''high'' level of stocks of raw materials rich in morphine.

Analysis of Thebaine-Rich Poppies

TABLE 2.—''GLOBAL CULTIVATION OF THEBAINE-RICH POPPIES (HECTARES) FOR LICIT PURPOSES OTHER THAN PRODUCTION OF OPIUM''

Country	2003 (ha)	2004 (ha)	2005 (ha-est.)	2006 (ha-est.)
Australia	7,637	5,578	6,500	5,300
People's Republic of China	34		40	50
France	1,499	1,007	1,100	1,000
Spain	.....	996	500	1,000
Total	9,170	7,581	8,140	7,350

Australia is the principal cultivator of thebaine-rich poppies and is responsible for the vast majority of thebaine-rich CPS that is produced and imported into the United States. Although the INCB notes that production of thebaine-rich NRM exceeded demand substantially until 2002, DEA notes that the primary cultivators, Australia and France, began decreasing areas under cultivation in 2003 and have made significant decreases since that time in order to bring production in line with utilization. Although Spain noted cultivation of thebaine-rich poppies for the first time in 2004, it is not responsible for excess production that resulted in excess supplies before then.

Consistency With the 80/20 Rule and International Resolutions

As stated in DEA's Notice of Proposed Rulemaking, the 80/20 rule was promulgated following a resolution adopted by the United Nations' Economic and Social Council (ECOSOC) in 1979. In response to the resolution in 1979, DEA published an Advance Notice of Proposed Rulemaking (44 FR 33695, June 12, 1979) and then a Notice of Proposed Rulemaking (45 FR 9289, February 12, 1980). The comments resulting from the Notice of Proposed Rulemaking led to an administrative hearing. On August 18, 1981, DEA published a final rule promulgating the 80/20 rule (46 FR 41775).

Objections to the current Notice of Proposed Rulemaking pointed to specific comments in the 1979 resolution, the Notice of Proposed Rulemaking, the transcript of the administrative hearing, and considerations made by then-Acting Administrator Francis Mullen, Jr., in DEA's 1981 Final Rule.

The foreign opiate manufacturer stated that the 1979 ECOSOC resolution called on ''importing countries to * * * take effective steps to support their traditional supplier countries'' and urged ''major producing and manufacturing countries to which have set up [sic] additional capacity in recent years to take effective measures to restrict substantially their production levels to assure a lasting balance between supply and demand and to prevent drug diversion to illicit channels.'' The commenter believed that ''[a]llowing Spain to now enter the market directly contradicts and undermines the objective of the Current 80/20 Rule, and rewards a country for engaging in the very conduct the Current 80/20 Rule, and the Resolutions, were intended to discourage or stop.''

The DEA-registered NRM importer who filed objections to the NPRM provided a summary of the determinations of fact made by Francis Young, the Administrative Law Judge (ALJ) who presided over the hearing in 1980; these findings were adopted by then-Acting Administrator Mullen when the final rule was promulgated. The DEA-registered importer provided the following summary of ALJ Young's determinations of fact: ''(1) DEA could lawfully promulgate the regulatory amendments limiting the importation of narcotic raw materials; (2) the Administrator of DEA could lawfully

require that a major portion of the [NRM] imported into the United States be produced in India and Turkey while permitting the remainder of the U.S. needs to be imported from other countries which maintain adequate control; (3) such allocation would be in harmony with U.S. trade agreements and would not be inconsistent with Resolution 471 and 497; and (4) DEA staff should determine an allocation ratio based upon world market shares during a recent representative period.'' This commenter further noted that the 1981 final rule ''established clearly stated criteria for selecting the other countries that could supply the United States market with NRM: (a) France, Hungary, Poland, and Yugoslavia 'provided the United States with [NRM] during the period 1975 through 1979 and present alternate sources' and Australia 'was the source of material for which import permits had been requested during the time period' and (b) Each country did 'impose adequate controls over their production of narcotic raw materials in adherence to their obligations under the Single Convention'.''

DEA Response: DEA disagrees with the commenters' assessments that this rule is inconsistent with the intent of the 80/20 rule and international resolutions. DEA finds that the proposed rule is consistent with both the 1979 resolution and the 80/20 rule.

Consistency with 1979 Resolution: The text of the 1979 resolution contained separate and distinct operative language for Governments of importing countries (i.e., the United States) and Governments of producer countries. The operative paragraph for importing countries:

> ''Urge[d] the Governments of the importing countries that have not already done so to take effective steps to support the traditional supplier countries and to give those countries all the practical assistance they can in order to prevent the proliferation of sources of production of narcotic raw materials for export[.]'' [6]

Neither DEA nor the commenters disagree that the United States meets the first prong of this operative paragraph, i.e., the support of ''traditional supply countries,'' by providing India and Turkey with access to at least 80 percent of the United States market for morphine contained in NRM. As has been stated throughout this rule, DEA remains committed to this obligation through its continued support of the 80/20 rule. The commenter's objections would, therefore, fall under United States' obligations under the second prong of this operative paragraph, namely to give all practical assistance in preventing the proliferation of producing countries. Since it is not refuted that the Government of Spain has been engaged in the production of NRM since 1974, prior to international calls to prevent proliferation, DEA concludes that the Government of Spain is not a new or emerging participant in the global production of NRM. The addition of Spain to the 80/20 rule will not result in a proliferation of producer countries. DEA therefore concludes that this action is consistent with the 1979 resolution.

Consistency with the 80/20 rule: As stated in the proposed rulemaking and reaffirmed in this final rule, DEA concludes that adding Spain to the list of countries authorized to export NRM to the United States is consistent with the 80/20 rule. Specifically, adding Spain is consistent with the criteria established by then-Acting Administrator Mullen when establishing Yugoslavia, France, Poland, Hungary, and Australia as the list of non-traditional suppliers in 1981. In the 1981 Final Rule, then-Acting Administrator Mullen stated:

> However, in view of the past commercial relations with certain other countries as sources of narcotic raw material supply and the desirability of preserving alternate sources of narcotic raw materials, it is appropriate to allow certain specific countries to compete for the U.S. narcotic raw materials market on a limited basis. These countries, France, Poland, Hungary and Yugoslavia have provided the United States with supplies of narcotic raw materials during the period 1975 and 1979 and represent appropriate alternate sources. Australia is included as well since it was the source of material for which import permits had been requested during that time period. In addition, we are presently persuaded that the nations mentioned above impose adequate controls over their production of narcotic raw materials in adherence to their obligations under the Single Convention. (46 FR 41775).

Then-Acting Administrator Mullen reaffirmed DEA's obligations to preserve alternate sources of NRM for the United States market. In an effort to determine the sources from which NRM could be derived, he established the following two criteria in designating the list of alternate sources: (1) The country had to have supplied the United States with NRM for a period of five years prior to the resolution's passage in 1979 and (2) the country had to have imposed adequate controls over the production of NRM consistent with its obligations under the Single Convention. In his decision, then-Acting Administrator Mullen created an exception to the first criterion; this exception allowed the Government of Australia to be added to the list of non-traditional suppliers. Specifically, then-Acting Administrator Mullen found that, if a country was not the source of imports during the period 1975–1979, then the country had to be a source from which DEA-registered importers of NRM had requested authority to import. Although Australia did not export NRM to the United States during the period 1975–1979, it was added because DEA-registered NRM importers had expressed interest in importing from Australia and had submitted to DEA the required ''Application for Permit to Import Controlled Substances for Domestic and/or Scientific Purposes'' (DEA–357) from Australia.

Based on this exception, one could conclude that Spain, despite not having been a source of NRM to the United States from 1975–1979, could qualify consistent with the 80/20 rule if a DEA-registered importer had expressed its interest in importing from Spain by filing a DEA–357, requesting authorization to do so. DEA notes, however, that the filing of such an application by a DEA-registered importer at present would be inconsistent with DEA regulations, specifically the 80/20 rule, and would therefore be impractical. Instead, interest in importing NRM from Spain arose through this rulemaking; DEA notes that one DEA-registered NRM importer expressed its interest in importing NRM from Spain during the comment period. DEA also notes that, during routine annual discussions with its five DEA-registered NRM importers before the receipt of the petition from the Government of Spain, the majority expressed some degree of interest in importing from Spain.

Neither the commenters nor DEA disagree with the statements of fact made by the Government of Spain that it has implemented a system of domestic controls for the handling of NRM that are consistent with the Single Convention; DEA concludes, as a result, that the second criterion has been satisfied.

DEA finds that adding Spain to the list of non-traditional suppliers is consistent with the criteria established in 1981 by then-Acting Administrator Mullen and is therefore consistent with the 80/20 rule.

Cost of Narcotic Raw Materials

One DEA-registered importer of NRM stated that DEA's Notice of Proposed

[6] Resolution 1979/8 of the Economic and Social Council. ''Maintenance of a world-wide balance between the supply of narcotic drugs and the legitimate demand for those drugs for medical and scientific purposes.''

Rulemaking ''will do little or nothing to improve adequacy of supply or the cost of NRMs for the U.S.'' The Government of Australia, in its comments to the DEA's proposed rule stated that ''Spain's petition presents no evidence to justify a need for change on the basis of adequacy of supply nor the cost effectiveness of that supply'' and that ''there is no real issue with cost.'' Finally, the foreign opiate manufacturer stated that there is no evidence that the proposed rule would maintain cost-effective supplies and that there is ''no suggestion that current supplies are not cost effective.''

DEA Response: DEA agrees that there is no evidence provided in the petition from Spain that the addition of Spain to the 80/20 rule would lead to more cost-effective supplies of NRM. This remains an open question. DEA does not routinely collect information relating to the cost of NRM or the opiates manufactured therefrom. Some of the commenters, however, provided data that demonstrate that the costs of NRM have steadily declined over the last five years and are presently at ''record lows.'' For example, the DEA-registered importer of NRM that objected to the NPRM stated that the price of CPS–M from Turkey was $660 per kilogram in 2001 and will be $300 per kilogram in 2007. The same commenter noted that CPS–T was $825 per kilogram in 2001 and will be $500 per kilogram in 2007. The foreign opiate manufacturer stated that, ''taking the United States supply price in 2001 as a benchmark, the 2006 average price of Thebaine to the United States has declined over 20%.'' Given the increasing demand for thebaine, the foreign opiate manufacturer contends that a decrease in price suggests a ''robust competitive environment.''

DEA disagrees with the implication made by the Government of Australia, however, in its statement that ''Spain's assertion that its inclusion would further an underlying policy objective of the 80/20 Rule by ensuring an adequate and reliable supply at a stable price is based on a premise that prices of NRM have not been stable.'' DEA concludes instead that the prices of NRM are directly related to the global stocks of these materials, which for more than the last 5 years have been in excess of global demand. For example, in the 2005 INCB publication, ''Narcotic Drugs: Estimated World Requirements for 2006—Statistics for 2004,'' the INCB reported that ''global production of opiate raw materials rich in morphine exceeded global demand considerably during the period 2002–2004.'' For opiate raw materials rich in thebaine, the INCB reported that ''the total supply (production and stocks) continued to be above global demand also for thebaine-rich raw materials * * * and that the balance between supply and demand will continue to be positive.'' DEA therefore concludes that the decrease in price noted by the commenters is more a function of excess supply rather than evidence of ''robust competition,'' for, as noted, Australia supplies the vast majority of the United States' demand for thebaine.

DEA further concludes that maintaining cost-effective supplies of NRM to the United States equates to striking a global balance between supply of and demand for NRM. For producer countries such as India, Turkey, Australia, France and Spain, this means reducing areas of cultivation in times when global supplies are in excess and increasing production (to the extent possible) if and when hardship arises in a producer country that results in global demand being in excess of supply. For consumer countries, such as the United States, this equates to: (1) Ensuring that there are an adequate number of sources from which to procure NRM during times in which supplies are not in excess, (2) communicating accurate estimates of United States requirements for NRM to authorized exporting countries, and (3) working with the international community, including the INCB, to ensure a global balance between supply and demand.

Replacing Yugoslavia With Spain

The Republic of Macedonia (Macedonia) forwarded a letter prepared by the only company licensed in Macedonia to purchase poppy straw and manufacture opiate alkaloids. The company raised concerns regarding DEA's comment in the NPRM that ''the successor states to the former Yugoslavia no longer produce NRM for export.'' The company disagreed with this observation, stating that Macedonia has been ''enjoying the rights arising out of the 80/20 rule for more than 25 years.'' The company therefore insisted that ''Yugoslavia can only be replaced on the list with its legitimate successor state Macedonia.'' A second commenter stated that DEA's proposed rule sought to ''replace Macedonia with Spain.'' Finally, a third commenter stated that DEA ignored ''the position of its [Yugoslavia's] clear successor state, namely Macedonia.''

DEA Response: DEA disagrees with those commenters that suggest that Macedonia is the de facto successor to Yugoslavia for purposes of the 80/20 rule. Macedonia became a sovereign country only after the dissolution of Yugoslavia. As a new country, Macedonia cannot automatically replace Yugoslavia in the 80/20 rule. Macedonia is but one of five countries that were created after the dissolution of Yugoslavia in the early 1990s. Any one of the five countries would be required to petition DEA if it wished to be added to the list of countries authorized to export NRM. DEA would then be required to review the merits of any such petition in a manner consistent with DEA's review of the petition filed by Spain.

DEA also disagrees with Macedonia's assessment that its manufacturers have ''enjoyed'' the rights arising from the 80/20 rule for the last 25 years. The company did not provide any statistical data to demonstrate previous sales to the United States or anticipated sales to the United States. In this regard, DEA conducted a review of import permits issued for NRM over the last five years and did not identify an occasion in which a United States importer requested authority to import NRM from Macedonia. Instead, according to the most recent statistics available from the INCB (statistics for 2004), Macedonia did not export opium, poppy straw, or concentrate of poppy straw from 2002 through 2004. Instead, Macedonia reported the exportation of small quantities of morphine and codeine, schedule II controlled substances whose importation into the United States is generally regarded as being prohibited by DEA regulations unless specifically requested in limited quantities for use exclusively in scientific research (21 CFR 1312.13).

Conclusion

Based on the comments received, statistical data on imports of NRM collected and analyzed by DEA pursuant to the Code of Federal Regulations, and reports from the INCB, DEA concludes that in order to continue to ensure an adequate supply of NRM necessary to meet the estimated medical, industrial, scientific, and research needs of the United States, for lawful export requirements, and for the maintenance of adequate stocks, it is appropriate to add Spain to the list of non-traditional countries permitted to export NRM to the United States.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), that he has reviewed this regulation, and by approving it certifies

that this regulation will not have a significant economic impact on a substantial number of small business entities. This rule imposes no new costs or burden on small entities. Rather, this rule adds Spain to the list of non-traditional countries permitted to export NRM to the United States, helping to ensure that United States importers and manufacturers will have access to, and be able to procure, supplies of NRM to meet legitimate United States medical, scientific, research, and industrial needs, to ensure maintenance of adequate reserve stocks, and to meet lawful export requirements. Additionally, this rule provides DEA registered importers with another source from which to purchase NRM which are utilized for the production of controlled substances used in the United States for medical purposes.

Executive Order 12866

The Deputy Assistant Administrator, Office of Diversion Control, further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). It has been determined that this is a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget.

Executive Order 12988

This rule meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This rule does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1312

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

■ For the reasons set out above, 21 CFR part 1312 is amended as follows:

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1312 continues to read as follows:

Authority: 21 U.S.C. 952, 953, 954, 957, 958.

■ 2. Section 1312.13 is amended by revising paragraphs (f) and (g) to read as follows:

§ 1312.13 Issuance of import permit.

* * * * *

(f) Notwithstanding paragraphs (a)(1) and (a)(2) of this section, the Administrator shall permit, pursuant to section 1002(a)(1) or 1002(a)(2)(A) of the Act (21 U.S.C. 952(a)(1) or (a)(2)(A)), the importation of approved narcotic raw material (opium, poppy straw and concentrate of poppy straw) having as its source:

(1) Turkey,

(2) India,

(3) Spain,

(4) France,

(5) Poland,

(6) Hungary, and

(7) Australia.

(g) At least eighty (80) percent of the narcotic raw material imported into the United States shall have as its original source Turkey and India. Except under conditions of insufficient supplies of narcotic raw materials, not more than twenty (20) percent of the narcotic raw material imported into the United States annually shall have as its source Spain, France, Poland, Hungary and Australia.

Dated: January 30, 2008.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. E8–2142 Filed 2–5–08; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0280; FRL–8346–9]

Clothianidin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of clothianidin in or on sugar beet roots, tops and molasses. Bayer CropScience requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective February 6, 2008. Objections and requests for hearings must be received on or before April 7, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0280. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Kable Bo Davis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: