animal drug regulations to reflect a change of sponsor's name from Altana, Inc., to Nycomed US, Inc.

DATES: This rule is effective December 26, 2007.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *david.newkirk@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Altana, Inc., 60 Baylis Rd., Melville, NY 11747, has informed FDA that it has changed its name to Nycomed US, Inc. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect these changes.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600 in the table in paragraph (c)(1), remove the entry for ''Altana, Inc.'' and alphabetically add a new entry for ''Nycomed US, Inc.''; and in the table in paragraph (c)(2), revise the entry for ''025463'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Nycomed US, Inc., 60 Baylis Rd., Melville, NY 11747.	025463
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
025463	Nycomed US, Inc., 60 Baylis Rd., Melville, NY 11747
* * * * *	

Dated: December 12, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–24974 Filed 12–21–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1312

[Docket No. DEA–276F]

RIN 1117–AB00

Reexportation of Controlled Substances

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

ACTION: Final rule.

SUMMARY: The Controlled Substances Export Reform Act of 2005 amended the Controlled Substances Import and Export Act to provide authority for the Drug Enforcement Administration (DEA) to authorize the export of controlled substances from the United States to another country for subsequent export from that country to a second country, if certain conditions and safeguards are satisfied. DEA is amending its regulations to implement the new legislation.

DATES: *Effective Date:* This rule is effective January 25, 2008.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Background

The Controlled Substances Export Reform Act of 2005 (Pub. L. 109–57) was enacted on August 2, 2005. The Act amends the Controlled Substances Import and Export Act (CSIEA) to provide authority for the Attorney General (and DEA, by delegation) [1] to authorize the export of controlled substances in schedules I and II, and narcotic controlled substances in schedules III and IV, from the United States to another country for subsequent export from that country to a second country, if certain conditions and safeguards are satisfied.

Previously under the CSIEA (prior to the 2005 legislation), there were no circumstances in which it was permissible to export a controlled substance in schedules I and II, or a narcotic controlled substance in schedules III and IV, for the purpose of reexport to another country. Such controlled substances could lawfully be exported only to the immediate country where they would be consumed.

The Controlled Substances Export Reform Act requires the following:

> Notwithstanding [21 U.S.C. 953] subsections (a)(4) and (c)(3), the Attorney General may authorize any controlled substance that is in schedule I or II, or is a narcotic drug in schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country, if each of the following conditions is met:
>
> (1) Both the country to which the controlled substance is exported from the United States (referred to in this subsection as the 'first country') and the country to which the controlled substance is exported from the first country (referred to in this subsection as the 'second country') are parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971.
>
> (2) The first country and the second country have each instituted and maintain, in conformity with such Conventions, a system of controls of imports of controlled substances which the Attorney General deems adequate.
>
> (3) With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country.
>
> (4) With respect to the second country, substantial evidence is furnished to the Attorney General by the person who will export the controlled substance from the United States that—
>
> (A) The controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; and
>
> (B) The controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country.
>
> (5) The controlled substance will not be exported from the second country.
>
> (6) Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States delivers to the Attorney General documentation certifying that such export from the first country has occurred.

[1] 28 CFR 0.100(b).

(7) A permit to export the controlled substance from the United States has been issued by the Attorney General.

21 U.S.C. 953(f).

DEA Proposed Implementation of the Controlled Substances Export Reform Act of 2005

To address the provisions of the Controlled Substances Export Reform Act of 2005, DEA published a Notice of Proposed Rulemaking (NPRM) (71 FR 61436, October 18, 2006). This rulemaking proposed amending DEA regulations to implement this new legislation. Most of the proposed amendments to the regulations either reiterated the new statutory provisions added by the 2005 Act or specified the procedural details for complying with the new statutory provisions. In three respects, however, the proposed rule contained substantive requirements not contained in the statute. The first additional proposed requirement was that the exporter notify DEA when the shipment for reexport has left the United States. The second additional proposed requirement was that the reexport from the first country to the second country take place within 90 days after the shipment leaves the United States. The third additional proposed requirement was that bulk materials undergo further manufacturing in the first country prior to being shipped to the second country. This was the same requirement contained in existing DEA regulations for reexports of nonnarcotic controlled substances in schedules III and IV and schedule V controlled substances (21 CFR 1312.27(b)(5)).

Comments Received

DEA received nine comments on the Notice of Proposed Rulemaking. Commenters included one pharmaceutical research and manufacturing association, seven manufacturers (including one represented by a law firm), and one member of the public. Most of the commenters generally supported the rulemaking, but had a variety of comments regarding certain aspects of the proposed rule. DEA has made certain modifications to the proposed rule in view of the comments. The comments, and DEA's responses, are discussed below.

Authority of DEA to issue substantive requirements not contained in the statute: One commenter asserted that DEA is without authority under the Controlled Substances Export Reform Act of 2005 ''to create new criteria'' and thus that this final rule should be limited to those substantive requirements mandated by Congress under the 2005 Act. In support of this contention, this commenter asserted that ''Congress was extraordinary [sic] specific in the Act on the conditions and criteria under which schedule I and II controlled substances may be exported for reexport.''

DEA Response: Under the CSIEA, Congress granted the Attorney General express authority to ''promulgate and enforce any rules, regulations, and procedures which he may deem necessary and appropriate for the efficient execution of his functions under [the CSIEA].'' (21 U.S.C. 871(b) (incorporated into the CSIEA by 21 U.S.C. 965)). This authority has been delegated to the DEA Administrator (28 CFR 0.100(b)). Thus, DEA has such rulemaking authority with respect to all provisions of the CSIEA, including amendments thereto, such as those made by the Controlled Substances Export Reform Act of 2005. Indeed, if DEA were without such general rulemaking authority, the agency would have no ability to issue any regulations implementing the Controlled Substances Export Reform Act of 2005, as the 2005 legislation itself contains no express delegation of regulatory authority. Accordingly, this final rule is being issued pursuant to DEA's general authority granted by Congress to promulgate regulations necessary and appropriate for the efficient enforcement of the CSIEA.

That Congress included in the 2005 legislation very specific criteria under which certain controlled substances may be reexported in no way precludes or limits DEA's general rulemaking authority under the CSIEA. This is illustrated by, among other things, reviewing the longstanding import and export provisions of the CSIEA (21 U.S.C. 952 and 953), which also contain great specificity. Notwithstanding this specificity in the statutes, DEA has promulgated a variety of regulations (21 CFR part 1312) that impose restrictions beyond those mandated by Congress.

Time for reexportation: In its NPRM, DEA proposed requiring that the reexport from the first country to the second country take place within 90 days after the shipment leaves the United States. Eight commenters disagreed with this proposed requirement, citing a variety of concerns.

Commenters who disagreed with the 90-day timeframe asserted that, in some cases, it can take longer than 90 days to complete the additional manufacturing and testing in the first country and to obtain the permit from the second country. Further, these commenters asserted that other controls required by the Controlled Substances Export Reform Act are sufficient to ensure proper reexportation of controlled substances.

One commenter asked that DEA, when evaluating time considerations, bear in mind the system of estimates imposed under the treaties and implement the reexport allowance in a manner that will ''prevent an accumulation of raw materials and distortion of estimates.''

DEA Response: DEA has considered the commenters' concerns and their explanations for those concerns. In addressing these comments, it is useful to begin with a reiteration of some important general principles. First, it should be noted that the United States has always been a world leader in promoting international and domestic control of narcotics and other controlled substances. As our nation is the world's largest producer of pharmaceutical controlled substances, the controls implemented by the United States play a crucial role in preventing diversion worldwide. Moreover, taking steps to prevent the United States from being a source of worldwide diversion directly benefits our country since a portion of the controlled substances diverted into illicit channels abroad can end up being sent back to the United States through illicit channels.

Another key principle is that, as one of the commenters suggested, reducing the accumulation of stocks of controlled substances tends to decrease the opportunity for, and likelihood of, diversion. It has long been recognized that the longer large supplies of controlled substances remain idly stockpiled, the greater the possibility of diversion. Consistent with these considerations, it should be noted that Congress, in enacting the 2005 legislation allowing for reexports, contemplated that ''[a]ll subsequent transfers of controlled substances would still be subject to strict oversight by the DEA and will require a permit from the Attorney General to prevent any potential abuse.'' 151 Cong. Rec. H6671 (July 27, 2005).

Given these principles, DEA strongly believes that, from an international drug control perspective, it is essential that the export from the first country to the second country occur in a finite period of time. The reexport allowance was not intended, and should not be construed, to allow the United States to become a source of stockpiling of controlled substances abroad for indefinite time periods. Moreover, without some limitation on the time controlled substances may remain in the first

country, a scenario could arise in which DEA has issued a permit authorizing a reexport, yet be without sufficient documentation to determine whether the shipment (i) has remained for many months in the first country without being reexported, (ii) has been improperly reexported to a different second country than that indicated on the reexport application, or (iii) was properly reexported to the second country but the reexporter failed to notify DEA within 30 days as required by the statute. As DEA noted in the NPRM, it can be inferred that one purpose of Congress' inclusion of the requirement that the United States exporter notify DEA within 30 days of the exportation from the first country to the second country is to provide a means for DEA to maintain an awareness of the status of shipments leaving the United States for reexport and thereby enhance the agency's ability to monitor and prevent diversion of such shipments. Requiring that there be a finite time within which the exportation from the first country to the second country must occur eliminates the possibility that DEA would be unable to ascertain the status of an approved reexport for an indefinite period of time.

Nonetheless, based on the comments received, DEA has decided to amend the regulation to double the time limit originally proposed. Under this Final Rule, the exportation from the first country to the second country may take place up to 180 days after the controlled substance was exported from the United States.

Use of National Drug Codes: Proposed § 1312.22(a) would require that applicants for export permits include the National Drug Code (NDC) number. One commenter suggested that the NDC number should only be required if the drug or product exported is listed with the U.S. Food and Drug Administration (FDA), because, this commenter asserted, some research compounds, reference standards, and samples are not required by the FDA to have an NDC number. Another commenter expressed its opinion that, based on FDA regulations, NDC numbers are not assigned to products for export, and countries outside the United States do not require NDC numbers, so the requirement to provide an NDC number on the DEA reexport permit application should be removed.

DEA Response: Requirements relating to NDC numbers are set forth in regulations issued by FDA. The NDC number consists of three parts: The labeler code, the product code, and the package code. Currently, FDA assigns the labeler code, and the product and package codes are assigned by the regulated industry within certain FDA parameters. On August 29, 2006, FDA published a Notice of Proposed Rulemaking [''Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs'' (Docket No. 2005N–0403, RIN 0910–AA49) (71 FR 51276)] proposing, among other things, requirements regarding NDC numbers.

In view of the comments, DEA is modifying the proposed rule to indicate that persons applying for a reexport permit must supply to DEA the NDC number of a drug in accordance with FDA regulations. DEA anticipates that the overwhelming majority of controlled substances that will be reexported under this Final Rule will have NDC numbers. However, the Final Rule has been modified so that, if no NDC number is required under FDA regulations for a drug being exported from the United States, the applicant for reexport will not be required to supply an NDC number.

System of controls of imports: Consistent with the 2005 legislation, proposed § 1312.22(c)(1) and (c)(2) would require the countries to which the controlled substance is exported to be parties to certain international conventions and to maintain, in conformity with such conventions, a system of controls that DEA deems adequate. In the text accompanying the proposed rule, DEA stated that DEA must be able to make the foregoing determinations based on the information contained in the permit application (DEA Form 161R). With respect to these aspects of the proposed rule, one commenter stated: ''[I]t will be extremely difficult for U.S. exporters to determine in advance of applying for an export permit (to reexport) which countries the DEA has determined maintain a system of controls that the agency 'deems adequate.' '' Another commenter requested ''that the permit application not require the applicant to certify that the country maintains a system of control of imports consistent with the requirements of the treaties.'' However, a third commenter stated that ''the export permit applicant should be able to state that to the best of their knowledge and belief, the country of ultimate consumption maintains a system of control of imports consistent with the requirements of the treaties.''

DEA Response: The requirements to which these comments pertain were specifically included in the Controlled Substances Export Reform Act, as codified in 21 U.S.C. 953(f)(1) and (2). These statutory requirements are repeated essentially verbatim in the text of the Proposed and Final rule (§ 1312.22(c)(1) and (c)(2)). However, in view of the comments, DEA wishes to clarify the following points. First, it was not DEA's intent to require the reexport permit applicant to certify that the first and second countries maintain systems of control which DEA deems adequate. Rather, as the statute indicates, *DEA* must make the determination—as a prerequisite to issuing the permit—that both the first and second countries are parties to the Single Convention and Psychotropic Convention and maintain, in conformity with such conventions, a system of controls of imports of controlled substances which DEA deems adequate. The applicant will be required to certify, on the DEA Form 161R, to the best of his/her belief, that ''the first and second countries have each instituted and maintain a system for the control of these substances.'' This is the same certification that traditional exporters have always been required to make under the DEA Form 161.

Responsible official: Proposed § 1312.22(c)(7) would require the documentation to DEA to be signed by ''the responsible company official.'' One commenter pointed out that large companies might have several persons who meet these requirements and recommended that the provision be changed to ''a responsible official.''

DEA Response: DEA agrees that there are circumstances in which companies might have more than one official authorized or permitted to sign documents providing the required information of DEA. Therefore, DEA is amending 21 CFR 1312.22(c)(7) and 1312.22(d)(6) to permit a responsible company official to sign the documents in question.

Further manufacture of bulk materials: Proposed § 1312.22(d)(1) would prohibit bulk substances from being reexported in the same form as they were exported from the United States, *i.e.*, the material must undergo further manufacturing processes. Two commenters requested definitions or clarifications of the terms ''further manufacturing'' and ''bulk materials.'' One commenter suggested that further manufacturing should include processing, packaging, or relabeling and that bulk materials should include bulk product, such as tablets, capsules, solutions, suspensions, etc. That commenter also requested clarification in the Final Rule that bulk dosage forms

may be reexported for labeling and packaging in the second country.

DEA Response: The Controlled Substances Act (CSA) defines ''manufacture'' as: ''the production, preparation, propagation, compounding, or processing of a drug or other substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of such substance or labeling or relabeling of its container'' (21 U.S.C. 802(15)). DEA believes that this definition established by Congress is broad enough to encompass all controlled substance manufacturing activities. The requirement in the Final Rule that further manufacturing of bulk material take place in the first country will be satisfied by any bona fide manufacturing activity that fits within the broad CSA definition of ''manufacture.'' As mentioned in the NPRM, this further manufacturing requirement is the same requirement that exists in the current regulations for the reexportation of nonnarcotic controlled substances in schedules III and IV, and of controlled substances in schedule V. Those regulations have been in place for many years, and are well-understood by the regulated industry. DEA believes that the intent of this regulation, and the definition of remanufacture, is clear; there is nothing in the export regulations to supersede or otherwise interpret the definition of ''manufacture'' and DEA does not believe that further clarification is warranted here.

Similarly, DEA believes that the concept of bulk substances is well-understood within the regulated industry and does not require further clarification. Congress used the term ''bulk manufacture'' in the CSIEA without defining that term, see 21 U.S.C. 958(i), and DEA has never attempted to define this term by regulation. DEA does not believe that the issuance of this rule necessitates such a definition. One example of how the term ''bulk manufacture'' has long been used by registrants without difficulty is that all persons who seek to become registered to manufacture schedule I and II controlled substances are required to specify on their applications for registration (DEA Form 225) whether they are seeking to engage in ''bulk'' manufacturing or some other type of manufacturing, such as dosage form manufacturing.

Reports of reexport to the second country: Proposed § 1312.22(d)(4) and (d)(5) would require the United States exporter to identify the second countries and quantities at the time of shipment. One commenter asserted that shifts in demand may occur after the product has been exported to the first country, so a list of second countries and potential quantities should be a permissible option. Another commenter believed that DEA should recognize that because of manufacturing processes in the first country, the amounts of reexports to the second country may vary from the original estimates. Thus, this commenter asserted that the Final Rule should allow the United States exporter to amend the 30-day export reports to keep DEA informed of changes.

DEA Response: While DEA recognizes that international demand for controlled substances may shift over time, the statute plainly contemplates that both the first and second country must be identified to DEA before the shipment leaves the United States in order for the agency to make the assessments required by the statute. Among other things, for DEA to meet its statutory and international treaty obligations, DEA cannot issue a permit for the exportation, or reexportation, of any controlled substance to any country when DEA has information to show that the estimates or assessments submitted with respect to that country for the current period, under the Single Convention on Narcotic Drugs, 1961, or the Convention on Psychotropic Substances, 1971, have been, or, considering the quantity proposed to be imported, will be exceeded. Thus, the permit issued by DEA authorizing the reexport must specify both the first and second countries and may not be modified to change the second country after the shipment leaves the United States.

Regarding variances in reexports to second countries due to manufacturing in the first country, it should be noted that the statute requires the applicant for reexport to provide DEA with substantial evidence, prior to the shipment leaving the United States, that a permit to import the controlled substance is to be issued by the second country and that the proposed amount of controlled substance to be reexported to the second country is needed for a medical, scientific, or other legitimate use in that country. Also, as indicated above and in the NPRM, the quantity of controlled substances must be such that the importing country will not exceed its estimates or assessments provided to the International Narcotics Control Board (INCB) of the United Nations. Thus, before any shipment leaves the United States for reexport, considerable planning and preparation should go into determining the quantity of controlled substances that is ultimately destined for the second country. Accordingly, there should be minimal variance between the quantity set forth in the export permit and that which is actually shipped to the second country. (DEA recognizes that there may be some slight wastage of controlled substances in manufacturing processes in the first country.)

Section 1312.22(c)(7) requires the United States exporter, within 30 days of exportation from the first country to the second country, to report to DEA on company letterhead the actual quantity shipped. Those who submit such reports will be reporting on quantifiable transactions that have already occurred and have a responsibility to provide accurate information in doing so. Therefore, amendments to this report should not be necessary.

Time to report reexportation: One commenter requested that DEA extend beyond 30 days the time required for the United States exporter to provide notification of reexports from the first country to the second country, because of the need to obtain information from other parties.

DEA Response: This requirement was set by Congress (21 U.S.C. 953(f)(6)) and DEA is without authority to modify it by regulation.

Return of the product to the United States: Proposed § 1312.22(d)(8) would provide for the reexporter to seek authorization from DEA to return a shipment to the United States if such shipment has been refused by the second country. One commenter urged DEA to allow the reexporter to seek the same return authorization where the shipment has been refused by the first country. This same commenter further asked that, if the shipment is refused by the second country, the reexporter be permitted to return the shipment to the first country. Two other commenters requested clarification as to whether the United States itself can serve as the second country.

DEA Response: As DEA discussed in the proposed rule, there are circumstances in which a shipment has been exported from the United States, but is refused by the consignee in the second country, or is otherwise unacceptable or undeliverable. In these circumstances, the exporter may seek permission from DEA, in appropriate circumstances, to return the shipment to the registered exporter in the United States. The language DEA proposed regarding this provision parallels the same language as is currently in place for reexportation of nonnarcotic controlled substances in schedules III

and IV, and controlled substances in schedule V. Under this provision, DEA will assess each situation on a case-by-case basis in determining whether it is appropriate to authorize the return of the shipment to the United States. DEA is adopting the first suggestion of the commenter to modify the rule to state expressly that if either the first or second country refuses the shipment, the reexporter may seek authorization from DEA to return the shipment to the United States. It should be noted, however, that DEA's experiences with reexportation of nonnarcotic controlled substances in schedules III and IV, and controlled substances in schedule V, indicate that such returns are expected to be very infrequent.

However, DEA cannot adopt the commenter's second suggestion—that DEA allow shipments which have been rejected by the second country to be returned to the first country. To do so would be the equivalent of allowing an export to the first country without having obtained proper approval before the shipment left the United States. Traditional exports of narcotic drugs in schedule I, II, III, or IV, and nonnarcotic controlled substances in schedule I or II are governed by 21 U.S.C. 953(a) and (c). Among the requirements of these provisions are: That DEA determine, before the shipment leaves the United States, that substantial evidence has been furnished that the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country of import; that there is an actual need for the controlled substance for medical, scientific, or other legitimate uses within the country; and that DEA has issued a permit to export the controlled substance for consumption in the country of import. In order for DEA to make these determinations, the applicant for the export permit must supply certain information and make certain certifications on DEA Form 161. None of the foregoing requirements would be satisfied if DEA allowed a shipment that it authorized for reexport to be returned from the second country to the first country. In addition, allowing such returns from the second country to the first country could potentially disrupt the system of estimates and assessments and statistical returns maintained by the INCB, which is crucial to international drug control.

Regarding whether the United States may serve as the second country, to allow controlled substances to be re-imported into the United States by interpreting the term ''second country'' to include the United States would be contrary to the intent of Congress in enacting the legislation. As stated in House Report 109–115, part 1, at 2 (2005): ''The purpose of this legislation is to amend Section 1003 of the Controlled Substances Import and Export Act [21 U.S.C. 953] by allowing a controlled substance that has been exported from the United States to be subsequently exported to a *third* country under certain conditions and pending a permit from the Attorney General.'' (Emphasis added.) Similarly, part 2 of the same House Report stated (at 2) that the legislation ''will allow pharmaceutical companies to export controlled substances to distribution centers for export to one *additional* country.'' (Emphasis added.) Along the same lines, in remarks made on the House floor upon moving to pass the Senate version of the bill (S. 1395), Congressman Deal stated:

> Under [then current law, as set forth in] the Controlled Substances Import and Export Act, a company is not allowed to export controlled substances to one country and then send it to a *third* country. Companies that export controlled substances must make a large number of long-distance, small shipments to individual countries, incurring large shipping costs. Due to this restriction, American manufacturers are less competitive than their foreign competitors, which results in high-paying U.S. jobs being sent overseas.

151 Cong. Rec. H6671 (July 27, 2005) (emphasis added).

Thus, the scenario that Congress sought to address through the legislation entails the exportation of controlled substance drug products manufactured (initially) in the United States for ultimate consumption abroad (i.e., in a ''third country'').

In addition, even if Congress had expressed no intent as to whether the ''second country'' referred to in 21 U.S.C. 953(f) could be the United States (which was not the case), re-importation into the United States would be impermissible unless the re-importer were able to demonstrate that it met the requirements of 21 U.S.C. 952(a)(2). Section 952(a)(2) governs importation of ''any controlled substance in schedule I or II or any narcotic drug in schedule III, IV, or V,'' which encompasses all the controlled substances subject to 21 U.S.C. 953(f), the Controlled Substances Export Reform Act. The requirements of § 952(a)(2) are highly restrictive and unlikely to be demonstrated where the applicant seeks to export a controlled substance from the United States for re-importation into the United States.

Estimated times per response for filing DEA Form 161 and 161R: As discussed in the preamble to the NPRM, DEA Form 161 is currently used to report the exportation of controlled substances in schedules I and II and narcotic controlled substances in schedules III and IV. DEA proposed the establishment of new Form 161R for the reporting of reexportations. The discussion of the Paperwork Reduction Act in the preamble to the proposed rule included a table of the estimated number of respondents and the amount of time estimated for an average respondent to respond regarding the completion of these forms. One commenter believed that the time estimates for completion of the required forms were too low because they apparently did not consider the time required to obtain the information needed to complete the forms. The commenter did not provide its own estimates regarding the time needed to complete the forms.

DEA Response: DEA estimates that it takes 30 minutes for a respondent to complete DEA Form 161 for exportation of controlled substances. DEA estimates that it takes a respondent 45 minutes to complete DEA Form 161R for reexportation of controlled substances. DEA recognizes that a variety of factors contribute to the time required to complete these forms including, but not limited to, the number and variety of controlled substances being exported or reexported, the number of countries to which controlled substances are exported or reexported, and the respondent's familiarity with the form. DEA notes that these estimates are average estimates; it may take some persons more time to complete these forms and it may take some less time. Therefore, as the time burdens are estimates of the time an average respondent takes to respond, and based on the varying factors associated with each exportation or reexportation of controlled substances, DEA believes that these estimates are accurate, on average, and is not adjusting the time burdens associated with this collection.

Other Considerations

Treaty Considerations

As discussed in the NPRM, the first two subsections of the Controlled Substances Export Reform Act of 2005 pertain to the Single Convention on Narcotic Drugs, 1961 (Single Convention), and the Convention on Psychotropic Substances, 1971 (Psychotropic Convention). Under these provisions, a reexport may take place only if both the first and second country are parties to both treaties and only if the Attorney General (DEA by delegation) determines that both the first country and the second country maintain an adequate system of controls in conformity with the treaties.

Thus, Congress expressly intended that reexports take place in accordance with the treaties. The control measures imposed under the Controlled Substances Export Reform Act of 2005, along with the regulations being finalized here, are intended to work in tandem with the international control regimes under the treaties. The ultimate goal of the 2005 Act and this Final Rule is to permit exportation of controlled substances in schedules I and II and narcotic controlled substances in schedules III and IV from the United States to a first country for subsequent exportation to one or more second countries while preventing international diversion resulting from reexports. Whenever considering safeguards against diversion of international shipments, one must bear in mind the backdrop of the treaties. Toward this end, the following treaty principles are noted.

Under the Single Convention, each country that is a party to the treaty is required to furnish the International Narcotics Control Board (INCB) with annual estimates of, among other things, the quantities of narcotic drugs on hand, the anticipated amounts that will be consumed by the party for legitimate purposes, and the anticipated production quantities. The Single Convention also requires parties to furnish the INCB with statistical returns for the prior year, indicating the amounts of drugs produced, utilized, consumed, imported, exported, seized, disposed of, and in stock. The Psychotropic Convention requires the parties to provide the INCB with statistical reports and assessments containing similar information with respect to psychotropic substances. Through the collection of this information, the INCB provides exporting countries with information on the legitimate requirements of the importing countries and can take steps to reduce the likelihood of international diversion. For example, the INCB may notify parties if the quantity of drugs exported to a particular country exceeded the estimates for that country. Parties that receive such notification from the INCB are prohibited from authorizing further exports of the drug concerned to that country.

Issuance of Permits

Under the 2005 Act, before a controlled substance can be exported for subsequent reexport, the exporter must obtain from DEA a permit that authorizes the export for this purpose. Consistent with the 2005 Act, DEA may issue such a permit only if each of the conditions specified in the Act is met. Each of these conditions is restated in this Final Rule. Although most of these conditions are self-explanatory, some additional explanation is warranted.

DEA will be issuing a new application form, DEA Form 161R, for a permit to export controlled substances for subsequent reexport in accordance with the 2005 Act. The statute requires the reexporter (as a condition of obtaining an export permit from DEA) to specify both the first and the second countries, and to provide substantial evidence that, with respect to the second country, the controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country. In its NPRM, DEA discussed what would constitute ''substantial evidence'' for purposes of subsection (4) of the 2005 Act. Specifically, if on the completed DEA Form 161R, the applicant has identified an appropriately licensed or permitted consignee in the second country and certified that the second country is a party to the Conventions and maintains a system of controls of imports consistent with the requirements of the treaties, and so affirmed in the affidavit section of the application, DEA will consider this substantial evidence that a permit or license to import the controlled substance will be issued by the second country.

Failure to comply with the CSIEA and its implementing regulations, including those set forth in this rulemaking, may result in the imposition of penalties and/or administrative remedies as provided in the CSIEA. As with all statutory and regulatory provisions that DEA administers, the agency will evaluate any transgressions involving this Final Rule on a case-by-case basis, taking into account the totality of the circumstances, in determining the appropriate course of action.

Reexportation to More Than One Second Country

DEA believes it is consistent with the text, structure, and purpose of the 2005 Act to allow a shipment of controlled substances to be exported from the United States to a ''first country'' for reexport to more than one ''second country'' (but not further export from any second country to a third country), provided the exporter notifies DEA of this intent in the application for export permit, and provided further that the statute is fully complied with in all other respects. DEA received one comment discussing this issue. The commenter supported DEA's position, agreeing that such an interpretation was contemplated in the Controlled Substances Export Reform Act. Therefore, this provision is being finalized without change. This Final Rule expressly provides for reexport to more than one second country, and the new Form 161R is structured accordingly.

Refused Shipments

As discussed previously, there are circumstances in which a shipment has been exported from the United States, but is refused by the consignee in the second country, or is otherwise unacceptable or undeliverable. In these circumstances, the exporter may seek permission from DEA, in appropriate circumstances, to return the shipment to the registered exporter in the United States. DEA proposed applying the same procedures to address this circumstance as already exist for the reexportation of nonnarcotic controlled substances in schedule III and IV, and controlled substances in schedule V (21 CFR 1312.27(b)(5)(iv)). DEA did not receive any comments seeking revision of this proposed language. Therefore, it is adopted as proposed.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), 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 entities. This rulemaking permits schedule I and II controlled substances, and narcotic controlled substances in schedules III and IV, to be exported from the United States to the first country for subsequent reexport to second countries for consumption. Previously such reexportation was not permitted within DEA law and regulations.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 § 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 regulation meets the applicable standards set forth in §§ 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking 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.

Paperwork Reduction Act of 1995

The Department of Justice, Drug Enforcement Administration, is revising the information collection entitled ''Application for Permit to Export Controlled Substances'', by adding a new DEA Form 161R to be used by persons applying for a permit to reexport controlled substances in schedules I and II, and narcotic controlled substances in schedules III and IV. DEA has submitted the new DEA Form 161R and the information collection request to the Office of Management and Budget for review and clearance in accordance with review procedures of the Paperwork Reduction Act of 1995.

Overview of this information collection

(1) *Type of Information Collection:* Revision of an existing collection.

(2) *Title of the Form/Collection:* Application for Permit to Export Controlled Substances.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:*

Form Number: DEA Form 161, Application for Permit to Export Controlled Substances; DEA Form 161R, Application for Permit to Export Controlled Substances for Subsequent Reexport.

Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: None.

Abstract: Title 21 CFR 1312.21 and 1312.22 require persons who export controlled substances in schedules I and II and who reexport controlled substances in schedules I and II and narcotic controlled substances in schedules III and IV to obtain a permit from DEA. Information is used to issue export permits, exercise control over exportation of controlled substances, and compile data for submission to the United Nations to comply with treaty requirements.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 90 respondents will respond, with submissions as follows:

	Number of responses	Average time per response	Total (hours)
DEA Form 161 (exportation only)	2,200	30 minutes (0.5 hours)	1,100
DEA Form 161R (reexportation)	400	45 minutes (0.75 hours)	300
Certification of exportation from United States to first country.	400	15 minutes (0.25 hours)	100
Certification of reexportation from first country to second country*.	1,200	15 minutes (0.25 hours)	300
Total	4,200		1,800

* Assumes three separate reexports to second countries

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total public burden (in hours) for this collection is estimated to be 1,800 hours.

Congressional Review Act

This rule is not a major rule as defined by § 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—[AMENDED]

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

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

■ 2. Section 1312.22 is amended by revising paragraph (a) and adding paragraphs (c) through (e) to read as follows:

§ 1312.22 Application for export permit.

(a) An application for a permit to export controlled substances shall be made on DEA Form 161, and an application for a permit to reexport controlled substances shall be made on DEA Form 161R. Forms may be obtained from, and shall be filed with, the Drug Enforcement Administration, Import/Export Unit, Washington, DC 20537. Each application shall show the exporter's name, address, and registration number; a detailed description of each controlled substance desired to be exported including the drug name, dosage form, National Drug Code (NDC) number (in accordance with Food and Drug Administration regulations), the Administration Controlled Substance Code Number as set forth in Part 1308 of this chapter, the number and size of packages or containers, the name and quantity of the controlled substance contained in any finished dosage units, and the quantity of any controlled substance (expressed in anhydrous acid, base, or alkaloid) given in kilograms or parts thereof. The application shall include the name, address, and business of the consignee, foreign port of entry, the port of exportation, the approximate date of exportation, the name of the exporting carrier or vessel (if known, or if unknown it should be stated whether shipment will be made by express,

freight, or otherwise, exports of controlled substances by mail being prohibited), the date and number, if any, of the supporting foreign import license or permit accompanying the application, and the authority by whom such foreign license or permit was issued. The application shall also contain an affidavit that the packages are labeled in conformance with obligations of the United States under international treaties, conventions, or protocols in effect on May 1, 1971. The affidavit shall further state that to the best of affiant's knowledge and belief, the controlled substances therein are to be applied exclusively to medical or scientific uses within the country to which exported, will not be reexported therefrom and that there is an actual need for the controlled substance for medical or scientific uses within such country, unless the application is submitted for reexport in accordance with paragraphs (c) and (d) of this section. In the case of exportation of crude cocaine, the affidavit may state that to the best of affiant's knowledge and belief, the controlled substances will be processed within the country to which exported, either for medical or scientific use within that country or for reexportation in accordance with the laws of that country to another for medical or scientific use within that country. The application shall be signed and dated by the exporter and shall contain the address from which the substances will be shipped for exportation.

* * * * *

(c) Notwithstanding paragraphs (a) and (b) of this section, the Administration may authorize any controlled substance listed in Schedule I or II, or any narcotic drug listed in Schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country, if each of the following conditions is met, in accordance with § 1003(f) of the Act (21 U.S.C. 953(f)):

(1) Both the country to which the controlled substance is exported from the United States (referred to in this section as the ''first country'') and the country to which the controlled substance is exported from the first country (referred to in this section as the ''second country'') are parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971;

(2) The first country and the second country have each instituted and maintain, in conformity with such Conventions, a system of controls of imports of controlled substances which the Administration deems adequate;

(3) With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country;

(4) With respect to the second country, substantial evidence is furnished to the Administration by the applicant for the export permit that—

(i) The controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; and

(ii) The controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country;

(5) The controlled substance will not be exported from the second country;

(6) The person who exported the controlled substance from the United States has complied with paragraph (d) of this section and a permit to export the controlled substance from the United States has been issued by the Administration; and

(7) Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States must deliver to the Administration documentation certifying that such export from the first country has occurred. If the permit issued by the Administration authorized the reexport of a controlled substance from the first country to more than one second country, notification of each individual reexport shall be provided. This documentation shall be submitted on company letterhead, signed by a responsible company official, and shall include all of the following information:

(i) Name of second country;

(ii) Actual quantity shipped;

(iii) Actual date shipped; and

(iv) DEA export permit number for the original export.

(d) Where a person is seeking to export a controlled substance for reexport in accordance with paragraph (c) of this section, the following requirements shall apply in addition to (and not in lieu of) the requirements of paragraphs (a) and (b) of this section:

(1) Bulk substances will not be reexported in the same form as exported from the United States, *i.e.*, the material must undergo further manufacturing process. This further manufactured material may only be reexported to a second country.

(2) Finished dosage units, if reexported, must be in a commercial package, properly sealed and labeled for legitimate medical use in the second country.

(3) Any proposed reexportation must be made known to the Administration at the time the initial DEA Form 161R is submitted. In addition, the following information must also be provided where indicated on the form:

(i) Whether the drug or preparation will be reexported in bulk or finished dosage units;

(ii) The product name, dosage strength, commercial package size, and quantity;

(iii) The name of consignee, complete address, and expected shipment date, as well as the name and address of the ultimate consignee in the second country.

(4) The application (DEA Form 161R) must also contain an affidavit that the consignee in the second country is authorized under the laws and regulations of the second country to receive the controlled substances. The affidavit must also contain the following statement, in addition to the statements required under paragraph (a) of this section:

(i) That the packages are labeled in conformance with the obligations of the United States under the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic Substances, 1971, and any amendments to such treaties;

(ii) That the controlled substances are to be applied exclusively to medical or scientific uses within the second country;

(iii) That the controlled substances will not be further reexported from the second country, and

(iv) That there is an actual need for the controlled substances for medical or scientific uses within the second country.

(5) If the applicant proposes that the shipment of controlled substances will be separated into parts after it arrives in the first country and then reexported to more than one second country, the applicant shall so indicate on the DEA Form 161R, providing all the information required in this section for each second country.

(6) Within 30 days after the controlled substance is exported from the United States, the person who exported the controlled substance shall deliver to the Administration documentation on the DEA Form 161R initially completed for the transaction certifying that such export occurred. This documentation

shall be signed by a responsible company official and shall include all of the following information:

(i) Actual quantity shipped;

(ii) Actual date shipped; and

(iii) DEA export permit number.

(7) The controlled substance will be reexported from the first country to the second country (or second countries) no later than 180 days after the controlled substance was exported from the United States.

(8) Shipments that have been exported from the United States and are refused by the consignee in either the first or second country, or are otherwise unacceptable or undeliverable, may be returned to the registered exporter in the United States upon authorization of the Administration. In these circumstances, the exporter in the United States shall file a written request for the return of the controlled substances to the United States with a brief summary of the facts that warrant the return, along with a completed DEA Form 357, Application for Import Permit, with the Drug Enforcement Administration, Import/Export Unit, Washington, DC 20537. The Administration will evaluate the request after considering all the facts as well as the exporter's registration status with the Administration. If the exporter provides sufficient documentation, the Administration will issue an import permit for the return of these drugs, and the exporter can then obtain an export permit from the country of original importation. The substance may be returned to the United States only after affirmative authorization is issued in writing by the Administration.

(e) In considering whether to grant an application for a permit under paragraphs (c) and (d) of this section, the Administration shall consider whether the applicant has previously obtained such a permit and, if so, whether the applicant complied fully with the requirements of this section with respect to that previous permit.

■ 3. Section 1312.23 is amended by revising paragraphs (a) and (f) to read as follows:

§ 1312.23 Issuance of export permit.

(a) The Administrator may authorize exportation of any controlled substance listed in Schedule I or II or any narcotic controlled substance listed in Schedule III or IV if he finds that such exportation is permitted by subsections 1003(a), (b), (c), (d), or (f) of the Act (21 U.S.C. 953(a), (b), (c), (d), or (f).

* * * * *

(f) No export permit shall be issued for the exportation, or reexportation, of any controlled substance to any country when the Administration has information to show that the estimates or assessments submitted with respect to that country for the current period, under the Single Convention on Narcotic Drugs, 1961, or the Convention on Psychotropic Substances, 1971, have been, or, considering the quantity proposed to be imported, will be exceeded. If it shall appear through subsequent advice received from the International Narcotics Control Board of the United Nations that the estimates or assessments of the country of destination have been adjusted to permit further importation of the controlled substance, an export permit may then be issued if otherwise permissible.

Dated: December 5, 2007.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9369]

RIN 1545–BG40

Calculating and Apportioning the Section 11(b)(1) Additional Tax under Section 1561 for Controlled Groups.

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document removes the final regulation for § 1.1561–2, amends §§ 1.1561–2T and 1.1563–1T, and adds § 1.1502–47T. These temporary regulations affect component members of a controlled group of corporations and consolidated groups filing life-nonlife Federal income tax returns. These temporary regulations provide guidance for calculating and apportioning between component members any amount of additional tax and any reduction in the amount exempted from the alternative minimum tax. These temporary regulations also update and clarify the allocation of tax-benefit items in the case in which a component member has a short taxable year not including a December 31st date. Finally, these temporary regulations provide explanations of two concepts: a group's testing date and a member's testing period for use in determining which members of the group and which taxable years of those members are subject to the controlled group rules. The text of these temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These temporary regulations are effective on *December 26, 2007.*

Applicability Dates: For the dates of applicability, see §§ 1.1502–47T(t)(1), 1.1561–2T(f)(1) and 1.1563–1T(e)(1). The applicability of these temporary regulations will expire on December 21, 2010.

FOR FURTHER INFORMATION CONTACT: Grid Glyer, (202) 622–7930 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

A. Summary of Limitations on Controlled Groups of Corporations Regarding Lower Tax Brackets and Alternative Minimum Tax Exemption Amounts

Section 1561(a) of the Internal Revenue Code (Code) provides that the *component members* of a *controlled group of corporations* (as those terms are defined in section 1563) are limited for their taxable years which include the same December 31st date to an amount of each of the tax-benefit items listed therein to which a corporation that is not a component member of a controlled group is entitled. Two of those items are the section 11(b)(1) tax-bracket amounts and the section 55(d)(2) exemption from the alternative minimum tax (the ''exemption amount''). See section 1561(a)(1) and (a)(3). Each of these two Code provisions requires reductions in calculating the amounts of each of these two tax-benefit items after the taxpayer has passed certain thresholds. The ''additional taxes'' under section 11(b)(1) serve to reduce a corporation's use of the lower tax brackets after certain specified threshold levels of income are reached. Section 55(d)(3) requires reductions to the amount exempted from the alternative minimum tax.

B. The Additional Taxes Imposed by Section 11(b)(1) and the Alternative Minimum Tax Exemption Amount

In general, section 11(b)(1) provides for a graduated income tax rate structure for taxing the income of a corporation. The income tax rates imposed on a corporation's income increase with each higher bracketed range of taxable income. The following chart shows the various tax rates imposed on a