However, the marking statute and regulations allow for exceptions to the marking requirements under certain circumstances. One of these exceptions concerns articles which cannot be marked prior to, or after, importation except at an expense that would be economically prohibitive. See 19 U.S.C. 1304(a)(3) (C) and (K), and 19 CFR 134.32(c) and (o). In consideration of: (1) The fact that many labels for assembled goods were already printed prior to July 1, 1996, on the basis of the current textile origin rules; (2) the expectation that many individual requests will be received for marking exceptions on the ground of economic prohibitiveness; and (3) the importance of providing uniformity of Customs treatment for such goods, Headquarters has made a general finding that it would be economically prohibitive to properly mark goods (either before or after importation) with respect to which marking labels have already been pre-printed or/or sewn into goods based on the current origin rules. This action will allow importers to exhaust their inventory of pre-existing labels stating ''Assembled in X country from U.S. components'' or a similar phrase, for goods that were assembled from components that were only cut to shape in the U.S. (i.e., not woven in the U.S.). This general marking exception shall be granted for all imported goods marked as described above for a period not to exceed four (4) months from the effective date of the new textile rule of origin (i.e., no later than November 1, 1996) which Customs views as a reasonable period of time for the exhaustion of existing inventory of labels. Please note that, if information is obtained that the above labels were printed after July 1, 1996, this general marking exception will not apply.

Dated: June 21, 1996.

Stuart P. Seidel,

Assistant Commissioner, Office of Regulations and Rulings.

[FR Doc. 96–16278 Filed 6–25–96; 8:45 am]

BILLING CODE 4820–02–P

Drug Enforcement Administration

21 CFR Parts 1309 and 1310

[DEA–133F]

RIN 1117–AA29

Waiver of Requirements for the Distribution of Prescription Drug Products Drug Products That Contain List I Chemicals

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA is amending its regulations to waive the registration requirement for persons who distribute prescription drug products that are subject to regulation on List I chemicals and to allow that the records required to be maintained pursuant to the Federal Food and Drug Administration (FDA) regulations for prescription drug products shall be deemed adequate for satisfying DEA's recordkeeping requirements with respect to distribution. In response from industry, DEA has conducted a review and determined that such prescription drug products are already subject to extensive regulatory controls regarding their distribution and there is no evidence that the products are being diverted at this time. This action will relieve distributors and manufacturers of regulated prescription drug products containing List I chemicals from the chemical control requirements in circumstances where compliance would be unnecessary for enforcement of the law.

EFFECTIVE DATE: July 26, 1996.

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

SUPPLEMENTARY INFORMATION: On September 26, 1995, DEA published a notice in the Federal Register (60 FR 49527) proposing to amend Title 21, Code of Federal Regulations (CFR), parts 1309 and 1310, to waive the requirement of registration for persons distributing prescription drug products that are regulated as List I chemicals and to allow that the records required to be maintained pursuant to the FDA regulations for prescription drug products shall be deemed adequate for satisfying DEA's recordkeeping requirements with respect to distribution. This rule responds industry's requests for relief based on existing regulatory controls and the lack of evidence of diversion of the products.

One comments was submitted in response to the proposed rulemaking. That comment, while supporting the proposed amendments, requested that DEA include in the regulations a provision that the FDA record retention requirement of two years, rather that the four year retention period required under the Controlled Substances Act (CSA), would apply to records of distributions of regulated prescription drug products. DEA is aware of the discrepancy between the record retention requirements between the FDA and DEA for these products; however, DEA does not have flexibility regarding the recordkeeping retention period for List I chemicals since 21 U.S.C. 830(a)(1)(A) of the CSA mandates that records of transactions involving List I chemicals shall be maintained for four years. There is no provision in the CSA allowing DEA the discretion to waive or modify that requirement. Only the Congress could amend the statute as proposed by the commentor. Until that requirement of the law is amended, records of regulated transactions involving List I chemicals must be maintained for the required four year period.

The Deputy Administrator of the Drug Enforcement Administration hereby certifies that this rulemaking will not have a significant impact on a large number of entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This rulemaking grants those persons who distribute regulated prescription drug products relief from DEA's chemical registration requirement and allows for the use of records already maintained pursuant to FDA regulations in lieu of requiring that separate records be maintained. These amendments could potentially ease the regulatory burden for 1,200 or more distributors and manufacturers of regulated prescription drug products.

This rule has been drafted and reviewed in accordance with Executive Order 12866. DEA has determined that this is not a significant regulatory action under the provisions of Executive Order 12866, section 3(f) and accordingly this rule has not been reviewed by the Office of Management and Budget. This rule will eliminate unnecessary regulatory requirements for distributors of regulated prescription drug products.

This action has been analyzed in accordance with the principles an criteria in Executive Order 12612, and it has been determined that the rule does not have sufficient federalism

implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, List I and List II chemicals, Security measures.

21 CFR Part 1310

Drug traffic control, List I and List II chemicals, Reporting and recordkeeping requirements.

For reasons set out above, 21 CFR parts 1309, and 1310 are amended as follows:

PART 1309—[AMENDED]

1. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 958

2. Section 1309.21 is revised to read as follows:

§ 1309.21 Persons required to register.

(a) Every person who distributes, imports, or exports any List I chemical, other than those List I chemicals contained in a product exempted under Section 1310.01(f)(1)(iv) of this chapter, or who proposes to engage in the distribution, importation, or exportation of any List I chemical, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§ 1309.24 through 1309.28 of this part. Only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation distributing List I chemicals is not required to obtain a registration.)

(b) Every person who distributes or exports a List I chemical they have manufactured, other than a List I chemical contained in a product exempted under § 1310.01(f)(1)(iv) of this chapter, or proposes to distribute or export a List I chemical they have manufactured, shall obtain annually a registration specific to the List I chemicals to be handled, unless exempted by law or pursuant to §§ 1309.24 through 1309.28 of this part.

3. Section 1309.22 is amended by revising paragraph (b) to read as follows:

§ 1309.22 Separate registration for independent activities.

* * * * *

(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities, unless otherwise exempted by the Act or Sections 1309.24 through 1309.28 of this part, except that a person registered to import any List I chemical shall be authorized to distribute that List I chemical after importation, but no other chemical that the person is not registered to import.

4. Section 1309.28 is added to read as follows:

§ 1309.28 Exemption of distributors of regulated prescription drug products.

(a) The requirement of registration is waived for any person who distributes a prescription drug product containing a List I chemical that is regulated pursuant to § 1310.01(f)(1)(iv) of this chapter.

(b) If any person exempted by this section also engages in the distribution, importation or exportation of a List I chemical, other than as described in paragraph (a) of this section, the person shall obtain a registration for such activities, as required by § 1309.21 of this part.

(c) The Administrator may, upon finding that continuation of the waiver granted in paragraph (a) of this section would not be in the public interest, suspend or revoke a person's waiver pursuant to the procedures set forth in § § 1309.43 through 1309.46 and 1309.51 through 1309.57 of this part.

PART 1310—[AMENDED]

5. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b)

6. Section 1310.06 is amended by revising paragraph (b) to read as follows:

§ 1310.06 Content of records and reports.

* * * * *

(b) For purposes of this section, normal business records shall be considered adequate if they contain the information listed in paragraph (a) of this section and are readily retrievable from other business records of the regulated person. For prescription drug products, prescription and hospital records kept in the normal course of medical treatment shall be considered adequate for satisfying the requirements of paragraph (a) of this section with respect to dispensing to patients, and records required to be maintained pursuant to the Federal Food and Drug Administration regulations relating to the distribution of prescription drugs, as set forth in 21 CFR part 205, shall be considered adequate for satisfying the requirements of paragraph (a) of this section with respect to distributions.

* * * * *

Dated: May 28, 1996.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

[FR Doc. 96–16299 Filed 6–25–96; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8675]

RIN 1545–AR04

Modifications of Debt Instruments

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the modification of debt instruments. The regulations govern when a modification is treated as an exchange of the original debt instrument for a modified instrument. The regulations provide needed guidance to issuers and holders of debt instruments.

DATES: These regulations are effective September 24, 1996.

For dates of applicability of these regulations, see § 1.1001–3(h).

FOR FURTHER INFORMATION CONTACT: Thomas J. Kelly, (202) 622–3930 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On December 2, 1992, proposed amendments to 26 CFR part 1 were published in the Federal Register (57 FR 57034) to provide guidance under § 1.1001–3. The proposed regulations relate to the modification of debt instruments. On February 17, 1993, the IRS held a public hearing on the proposed regulations. In addition, the IRS received numerous written comments on the proposed regulations. The proposed regulations, with certain changes made in response to comments, are adopted in this Treasury decision as final regulations. The principal changes to the regulations, as well as the major comments and suggestions, are discussed below.

Explanation of Provisions

A. General

The preamble to the proposed regulations states that the proposed