all adverse experiences that are the subject of these postmarketing 15-day Alert reports and shall submit followup reports within 15 calendar days of receipt of new information or as requested by FDA. If additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information. Postmarketing 15-day Alert reports and followups to them shall be submitted under separate cover.

(iii) *Submission of reports.* The requirements of paragraphs (c)(1)(i) and (c)(1)(ii) of this section, concerning the submission of postmarketing 15-day Alert reports, shall also apply to any person whose name appears on the label of a licensed biological product as a manufacturer, packer, distributor, shared manufacturer, joint manufacturer, or any other participant involved in divided manufacturing. To avoid unnecessary duplication in the submission to FDA of reports required by paragraphs (c)(1)(i) and (c)(1)(ii) of this section, obligations of persons other than the licensed manufacturer of the final biological product may be met by submission of all reports of serious adverse experiences to the licensed manufacturer of the final product. If a person elects to submit adverse experience reports to the licensed manufacturer of the final product rather than to FDA, the person shall submit each report to the licensed manufacturer of the final product within 5 calendar days of receipt of the report by the person, and the licensed manufacturer of the final product shall then comply with the requirements of this section. Under this circumstance, a person who elects to submit reports to the licensed manufacturer of the final product shall maintain a record of this action which shall include:

(A) A copy of all adverse biological product experience reports submitted to the licensed manufacturer of the final product;

(B) The date the report was received by the person;

(C) The date the report was submitted to the licensed manufacturer of the final product; and

(D) The name and address of the licensed manufacturer of the final product.

(iv) *Report identification.* Each report submitted under this paragraph shall bear prominent identification as to its contents, i.e., ''15-day Alert report,'' or ''15-day Alert report-followup.''

* * * * *

(f) *Reporting forms.* (1) Except as provided in paragraph (f)(3) of this section, the licensed manufacturer shall complete the reporting form designated by FDA for each report of an adverse experience (FDA Form 3500A, or, for vaccines, a VAERS form; foreign events including those associated with the use of vaccines, may be submitted either on an FDA Form 3500A or, if preferred, on a CIOMS I form).

* * * * *

(g) *Multiple reports.* A licensed manufacturer should not include in reports under this section any adverse experience that occurred in clinical trials if they were previously submitted as part of the license application. * * *

* * * * *

Dated: September 25, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–26255 Filed 10–6–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309, 1310 and 1313

[DEA Number 154F]

RIN 1117–AA42

Implementation of the Comprehensive Methamphetamine Control Act of 1996; Possession of List I Chemicals Definitions, Record Retention, and Temporary Exemption From Chemical Registration for Distributors of Combination Ephedrine Products

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: DEA is finalizing the Interim Rule, which included a request for comment, published in the **Federal Register** on February 10, 1997, (62 FR 5914). The Interim Rule amended the regulations to incorporate certain amendments to the Controlled Substances Act (CSA) made by the Comprehensive Methamphetamine Control Act of 1996 (MCA) and to provide temporary exemption from registration for persons who distribute combination ephedrine products. Comments were received regarding industry interpretation of certain requirements of both the CSA and the MCA. This notice responds to those comments and clarifies the requirements of the CSA and MCA with respect to the distribution of combination ephedrine products.

EFFECTIVE DATE: October 7, 1997.

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

SUPPLEMENTARY INFORMATION: On February 10, 1997, DEA published an interim rule, with request for comment, in the **Federal Register** (62 FR 5914) to implement certain regulatory changes mandated by the MCA and to provide temporary exemption from registration pending promulgation of final regulations to implement the MCA.

Five comments were received regarding the interim rule. Three separate issues were raised in the comments:

(1) Two comments expressed support for the temporary exemptions and urged that the exemption from registration for retail distributors as described in the MCA be made permanent. DEA agrees and will make the exemption permanent.

(2) Three comments asserted that DEA's interpretation of the MCA is incorrect and that the registration requirement does not apply to wholesale distributors that engage in only sub-threshold transactions of combination ephedrine products.

Specifically, the commentors assert that while Section 302(a)(1) of the CSA (21 U.S.C. 822(a)(1)) requires that any person who distributes a List I chemical must register, that requirement is tempered by Section 303(h) of the CSA (21 U.S.C. 823(h)), which provides, in part, that registration shall not be required for the distribution of a drug product that is exempted under section 102(39)(A)(iv). Section 102(39) of the CSA (21 U.S.C. 802(39)) defines the term ''regulated transaction''. The definition provides in paragraph (A)(iv) that a transaction in a listed chemical contained in a drug product that may be marketed or distributed under the Food, Drug, and Cosmetic Act (FDC Act) is not a regulated transaction, unless the drug contains ephedrine, pseudoephedrine, or phenylpropanolamine, and the quantity of ephedrine, pseudoephedrine, or phenylpropanolamine equals or exceeds the threshold established for the chemical. These provisions are echoed in DEA's regulations; Title 21, Code of Federal Regulations (CFR), Section 1309.21(a) requires registration for the distribution of a List I chemical, other than a List I chemical contained in a drug product that is exempted under 21 CFR section 1310.01(f)(1)(iv). The commentors assert the definition of regulated transaction provides that a

drug product remains exempt if the amount of List I chemical involved in the transaction is less than the threshold established for that chemical. Under the circumstances, the commentors argue that persons who engage only in sub-threshold distributions of List I chemicals contained in drug products are exempt from the registration requirement.

The commentors analysis of the referenced portions of the law fails to acknowledge certain points of law that must be considered in determining who must register.

First, the MCA amends existing language to remove the exemption for combination ephedrine products. The specific language that is subject to the commentors analysis (21 U.S.C. 802(39)(A)(iv) (I) and (II) and 21 U.S.C. 823(h)) was added to the CSA by the Domestic Chemical Diversion Control Act of 1993 (DCDCA).

A review of the legislative history of the DCDCA reveals that, as described in a letter of support for the DCDCA from the then Acting Administrator of DEA to the Chairman of the House Committee on Energy and Commerce, the registration system established under that act was ''* * * precisely patterned after the system which we have successfully employed for handlers of controlled substances since 1971.'' (U.S. Congressional and Administrative News, 103rd Congress, Vol. 4, Page 2986) The registration system for handlers of controlled substances, while providing for the exemption of certain products that contain controlled substances, does not consider the quantity involved in a distribution when determining whether registration is required; either the product is exempt or non-exempt. Thus, 21 U.S.C. 823(h) provides that the exemption from registration applies to exempted products, and not, as the commentor apparently reads it, to selective exempted distributions. In addition, the House Report No. 103–379, relating to the bill (H.R. 3216) which subsequently was enacted as the DCDCA, states ''This provision removes the exemption from record-keeping and reporting requirements of the Controlled Substances Act (CSA) for drugs containing ephedrine as the only active medicinal ingredient * * * It also removes the exemption for ephedrine products containing therapeutically insignificant quantities of other active ingredients.'' [emphasis added] At the time the DCDCA was enacted, the established threshold for ephedrine in any form was one kilogram. As Congress did not mention thresholds in its discussion of the exemption from registration created by the 1993 amendments, it follows that in enacting 21 U.S.C. 823(h), it meant the exemption from registration to apply to drug products themselves, rather than to transactions in drug products. Exempt products are not subject to the CSA's system of thresholds; therefore, thresholds had no relevance to the discussion.

Therefore, a distributor who distributes any amount of a List I chemical, including a drug product that is not exempt, is subject to the registration requirement.

Two additional points were raised in this matter by the commentors. The first dealt with the claimed inconsistency in DEA's determination to exempt retail distributors from the registration requirement and not exempt wholesale distributors if they engage solely in sub-threshold sales. These commentors stated that since retail distributors, by definition, limit sales to sub-threshold levels, wholesale distributors who limit sales to the substantially higher thresholds for wholesalers should also be exempt from registration.

There is no inconsistency in DEA's decision. The United States Congress, with the substantial participation of the affected industries, developed the MCA with the intent of providing controls to prevent the diversion of products to the illicit manufacture of methamphetamine, while not unnecessarily interfering with legitimate public access to the products at the retail level.

The MCA does not make any pretense of amending the existing chemical registration and recordkeeping requirements under the CSA, as amended by the CDTA and DCDCA. The principal effect of the MCA is the removal of the exemption for pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products, making these products subject to the controls under the CSA that apply to all List I chemicals. Thus, as with any other List I chemical, any person who distributes, imports, or exports any amount of these products will be subject to the chemical registration requirement and, to the extent that the transaction(s) meet the threshold criteria, the chemical recordkeeping and reporting requirements.

Within this framework, the MCA specifically establishes in the CSA the unique category of 'retail distributor' which is distinct from all other distributors of List I chemicals. A retail distributor is defined as a ''* * * person whose activities as a distributor relating to pseudoephedrine or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.'' The MCA further provides that the ''* * * sale of ordinary over-the-counter pseudoephedrine or phenylpropanolamine products by retail distributors shall not be a regulated transaction * * *'' [emphasis added]. These provisions clearly establish Congress' intent that public access to the products at the retail level be protected and that the protection applies only to one specific type of activity carried out by one specific type of distributor. It is equally clear, given the absence of any corresponding provisions in the MCA for other distributors, that the existing chemical controls, including registration, apply to the activities of all other distributors.

DEA recognized that the threat of diversion from the retail level would be minimized by adherence to the 24 gram per transaction threshold and that this reduced threat does not now justify the potential impact that the chemical controls might have on legitimate public access to the products at the retail level. Thus, DEA determined that an exemption from the registration requirement for retail distributors of combination ephedrine products who engage exclusively in sub-threshold transactions was consistent with the intent of the MCA that legitimate public access to drug products at the retail level be protected.

The absence of any exceptions in the MCA for non-retail distributors, coupled with the much larger thresholds (1 kilogram for combination ephedrine products and pseudoephedrine and 2.5 kilograms for phenylpropanolamine); the need to balance the lack of controls over transactions at the retail level with controls at the wholesale level; and the fact that it has been DEA's experience that the most efficient and effective means to identify and control diversion from the retail and wholesale levels is through application of the controls at the wholesale level, all pointed to the need to maintain the registration requirement envisioned by the MCA at the wholesale level.

The second concern dealt with the lack of a comprehensive listing identifying all of the products that contain ephedrine, and the difficulties that distributors could encounter in terms of identifying regulated products and complying with the chemical control requirements. DEA recognizes that in the absence of a 'closed system' of distribution as exists for controlled

substances, the identification of products that may be subject to regulation is more difficult. DEA will, where possible, work with the industry to assist in identification of such products. Further, the MCA makes all products containing ephedrine subject to regulation. Manufacturers of such products will have to obtain their distributor customers DEA registration numbers prior to distributing the products, which should assist in identifying products that are subject to regulation.

(3) Two comments asserted that the MCA exemption for sales of ordinary over-the-counter pseudoephedrine and phenylpropanolamine products by retail distributors and EAS's general exemption for retail distributors (21 CFR 1309.29) should also apply to distributions to the retail distributors by warehouses that are owned or operated by the owner of a retail chain. The commentors argue that the definition of retail distributors should encompass the entire retail distribution system, which includes both the retail outlets and the warehouses or storage facilities which are owned or operated by the same corporate entity that owns the retail outlets. They state that the distributions from the warehouses or storage facilities are not sales but transfers or intracompany sales within the retail distributor operation that are related to the retail sales of the products. One commentor last noted that within their industry warehouses and storage facilities are classified within the same Standard Industrial Classification (SIC) code that the MCA references in the definition for the retail outlets.

The MCA provides that the ''* * * sale of ordinary over-the-counter pseudoephedrine or phenylpropanolamine products by retail distributors shall not be a regulated transaction * * *''. MCA, Section 401(b)(1); 21 U.S.C. 802(39)(A)(iv)(I)(aa). The MCA defines 'retail distributor' as ''* * * a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to pseudoephedrine or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.'' (emphasis added] MCA Section 401(b)(4); 21 U.S.C. 802(46). 'Sales for personal use' is defined as ''* * * the sale of below-threshold quantities in a single transaction to an individual for legitimate medical use.'' MCA 401(b)(4); 21 U.S.C. 802(46)(B).

The definitions printed above describe the activities that a retail distributor may engage in with sufficient detail to establish the type of transactions that are to be exempted from regulation. The MCA provides that the exemption shall apply to sales by persons whose activities are limited almost exclusively to sales to individuals for legitimate medical use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. This language clearly does not contemplate an exception for a major class of wholesale distributions.

Further, the assertion that retail distributor should be defined as the corporate entity that is engaged in the process of retail distribution fails to acknowledge the requirements of the CSA with respect to separate registration for separate locations. The chemical registration requirements parallel the registration requirements established for controlled substances handlers; under such requirements, each location at which List I chemicals are distributed, imported, or exported must be viewed individually, as a separate person, for purposes of application of the chemical controls under the CSA.

Under the circumstances, the MCA cannot be read as providing an exemption for warehouses or storage facilities that operate within a retail distribution system. The MCA recognizes, quite logically, that if one portion of the distribution chain is to be granted exemption from regulation, then the other portion of the chain must be subject to control to insure that the distribution chain does not become a source of supply for the methamphetamine traffickers.

DEA does wish to note that in addition to receiving comments regarding registration for distributors of sub-threshold amounts of product and registration for distributors within retail distribution chains, the agency was also approached directly by the commentors for clarification of the requirements in each case. At the same time that this notice was drafted, individual responses were also provided directly to the commentors in response to their requests for clarification. While it may appear unusual for DEA to respond directly to persons regarding issues that have been raised in formal comments submitted in response to a rulemaking notice, it should be noted that neither concern has a direct bearing on the substance of the interim rule. The question of registration of distributors of sub-threshold amounts of product involves interpretation of the registration requirements established under the DCDCA in 1993; the MCA is only peripherally involved through its removal of the exemption from regulation for pseudoephedrine, phenylpropanolamine, and combination ephedrine products, subjecting them to the existing registration requirements. The question of registration for distributors within the retail distribution system involves clarification of a specific provision of the law which does not require any additional regulatory provisions to implement beyond technical amendments to make the language of the regulations consistent with the language of the law. Further, it was necessary that the requestors be given clarification of these points as quickly as possible to insure that the affected distributors could be advised as to the need to submit applications for registration prior to the deadline.

Following the close of the comment period of April 11, 1997, DEA received a written request, dated April 17, 1997, for an extension of the filing deadline for the temporary exemption in 21 CFR 1310.09. The requestor, a representative of a segment of industry heretofore not subject to DEA's chemical controls, cited industry misunderstandings regarding the registration requirements of the CSA and DEA's administration of the chemical control program in justifying the need for an extension of the deadline. DEA recognized that there had been confusion in the industry regarding the application of certain requirements under the MCA; therefore, the application deadline for temporary exemption was extended to July 12, 1997.

Accordingly, DEA's interim rule, published on February 10, 1997 (62 FR 5914), and amended on May 21, 1997 (62 FR 27693), is being adopted as a final rule.

The Deputy Assistant Administrator for the Office of Diversion Control hereby certifies that this rulemaking will not have a significant economic impact upon a substantial number of entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This rulemaking is an administrative action to make the regulations consistent with the law and to avoid interruption of legitimate commerce by granting temporary exemptions from registration pending promulgation, through notice and comment, of the regulations necessary to implement the provisions of the MCA pertaining to combination ephedrine products. Further, since this is a temporary action which provides affected persons with a means to

comply with the law pending promulgation of regulations implementing the MCA, this action is not a significant regulatory action and therefore has not been reviewed by the Office of Management and Budget pursuant to Executive Order 12866. Consideration of the significant and impact of the new requirements of the MCA will be addressed as part of a future notice by DEA proposing regulations to implement the MCA.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of Federalism Assessment.

This rule will not resulting the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more 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.

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. 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.

Accordingly, the interim rule amending 21 CFR parts 1309, 1310, and 1313, which was published at 62 FR 5914 on February 10, 1997, and amended at 62 FR 27693 on May 21, 1997, is adopted as a final rule.

Dated: September 29, 1997.

John H. King,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 97–26177 Filed 10–6–97; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 53

[TD 8736]

RIN 1545–AU66

Time for Filing Form 4720 Return

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains a regulation that specifies the filing date by which Form 4720 returns must be filed by disqualified persons and organization managers liable for Internal Revenue Code section 4958 excise taxes. These excise taxes are imposed on excess benefit transactions between disqualified persons and section 501(c)(3) organizations (except for private foundations) or section 501(c)(4) organizations.

DATES: This regulation is effective October 7, 1997.

For dates of applicability, see § 53.6071–1(f).

FOR FURTHER INFORMATION CONTACT: Phyllis Haney, (202) 622–4290 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Foundation and Similar Excise Taxes regulations (26 CFR part 53) under Internal Revenue Code (Code) section 6071. Those amendments provide guidance on the time for filing the return that is required to accompany payment of section 4958 excise taxes. This rule was first published in Notice 96–46 (1996–39 I.R.B. 7) (September 23, 1996). A notice of proposed rulemaking (NPRM) of that rule was published at 62 FR 84, by cross reference to a temporary regulation, (TD 8705, 62 FR 25), on January 2, 1997. The deadline for comments on the NPRM was April 2, 1997; no comments were received.

Taxpayer Bill of Rights 2, Public Law 104–168, 110 Stat. 1452 (TBOR2), enacted July 30, 1996, added section 4958 to the Code, which imposes excise taxes on excess benefit transactions. Section 4958 taxes apply retroactively to excess benefit transactions occurring on or after September 14, 1995. The taxes do not, however, apply to any benefit arising from a transaction pursuant to any written contract which was binding on September 13, 1995, and at all times thereafter before such transaction occurred.

An ''excess benefit transaction'' subject to tax under section 4958 is any transaction in which an economic benefit is provided by an organization described in Code section 501(c)(3) (except for a private foundation) or 501(c)(4) directly or indirectly to, or for the use of, any disqualified person if the value of the economic benefit provided exceeds the value of the consideration (including the performance of services) received for providing the benefit. A ''disqualified person'' is any person who was, at any time during the 5-year period ending on the date of the excess benefit transaction, in a position to exercise substantial influence over the affairs of the organization. Disqualified persons also include family members and certain entities in which at least 35 percent of the control or beneficial interest are held by persons described in the preceding sentence.

Code section 4958 imposes three taxes. The first tax is equal to 25 percent of the excess benefit amount, and is to be paid by any disqualified person who engages in an excess benefit transaction. The second tax is equal to 200 percent of the excess benefit amount, and is to be paid by any disqualified person if the excess benefit transaction is not corrected within the taxable period. The third tax is equal to 10 percent of the excess benefit amount, and is to be paid generally by any organization manager who knowingly participates in an excess benefit transaction. The maximum amount of this third tax with respect to any one excess benefit transaction may not exceed $10,000. An ''organization manager'' is any officer, director, trustee, or any individual having powers or responsibilities similar to those of any officer, director, or trustee. Final regulations under Code section 6011 were published on January 2, 1997, at TD 8705 (62 FR 25), prescribing Form 4720 for calculating and paying the first and third taxes described above.

TBOR2 also amended Code section 6033(b) to require section 501(c)(3) organizations to report the amounts of the taxes paid under section 4958 with respect to excess benefit transactions involving the organization, as well as any other information the Secretary may require concerning those transactions. Section 6033(f) also was amended to impose the same reporting requirements on section 501(c)(4) organizations. Those amendments to section 6033 only apply to organizations' returns for taxable years beginning after July 30, 1996. These and other TBOR2 amendments to the reporting requirements for section 501(c)(3) and section 501(c)(4) organizations are