

Dated: May 7, 1997.

**Robert C. Livingston,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

#### 21 CFR Part 1310

[DEA-154E]

RIN 1117-AA42

#### Temporary Exemption From Chemical Registration for Distributors of Combination Ephedrine Products; Extension of Application Deadline

**AGENCY:** Drug Enforcement Administration (DEA), Justice.

**ACTION:** Interim rule.

**SUMMARY:** DEA is amending its regulations to extend the temporary exemption from the chemical registration requirements from May 12, 1997 to July 12, 1997. Certain segments of the industry that distribute combination ephedrine products did not realize that they would be subject to the registration requirement due to questions regarding the application of the registration requirements to their activities. Persons failing to meet the May 12, 1997 deadline would have been required to cease all distributions of combination ephedrine products until they had obtained a registration. In order to avoid interruption of legitimate distributions of combination ephedrine products, based upon the request of this industry group, DEA is extending the temporary exemption from the registration requirement for the additional period to allow affected persons sufficient time to make application for registration.

**EFFECTIVE DATE:** May 21, 1997. The new deadline for submitting an application for registration is July 12, 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) 307-4025.

**SUPPLEMENTARY INFORMATION:** The Comprehensive Methamphetamine Control Act of 1996 (MCA) removed the exemption from DEA's chemical controls for combination ephedrine drug products, effective October 3, 1996. As a result, these products became subject to the chemical registration, recordkeeping, and reporting

requirements set forth in Title 21, Code of Federal Regulations (CFR), parts 1309, 1310, and 1313.

To allow businesses to continue to distribute combination ephedrine products pending issuance of a registration to engage in such activities, DEA amended its regulations by interim rule published in the **Federal Register** on February 10, 1997 (62 FR 5914) to provide that any person who submitted a properly completed application for registration to DEA on or before May 12, 1997, would be exempt from the registration requirement until DEA took final action on such application (21 CFR 1310.09).

Following publication of the interim rule, questions were raised by a segment of the industry distributing combination ephedrine products regarding whether the registration requirements applied to their activities. Following clarification of the chemical registration requirements, a request was received from Food Distributors International for an extension of the application deadline to allow adequate time for the affected distributors to make application for registration. DEA has no objection to granting the request. Therefore, 21 CFR 1310.09 is being amended to provide that the deadline for submitting an application is extended to July 12, 1997.

The Acting Deputy Administrator of the Drug Enforcement Administration hereby certifies that this interim rulemaking will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This interim rulemaking extends a temporary exemption from the registration requirement for distributors of combination ephedrine products.

This rule is not a significant regulatory action and therefore has not been reviewed by the Office of Management and Budget pursuant to Executive Order 12866.

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

#### List of Subjects in 21 CFR Part 1310

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

For reasons set out above, Title 21, Code of Federal Regulations, part 1310 is amended as follows.

#### PART 1310—[AMENDED]

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

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

2. Section 1310.09 is revised to read as follows:

#### § 1310.09 Temporary exemption from registration.

Each person required by Section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a combination ephedrine product is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before July 12, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

Dated: May 14, 1997.

**James S. Milford,**

*Acting Deputy Administrator.*

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## DEPARTMENT OF STATE

### Bureau of Consular Affairs

#### 22 CFR Part 42

[Public Notice 2546]

#### Visas: Documentation of Immigrants Under the Immigration and Nationality Act; Validity of Immigrant Visas

**AGENCY:** Bureau of Consular Affairs, Department of State.

**ACTION:** Final rule.

**SUMMARY:** On September 30, 1996, the Immigration and Nationality Act (INA) was amended to, inter alia, grant authority to the Secretary of State to extend the period of validity of an immigrant visa to six months from the date of issuance. The Secretary of State, hereby, exercises that authority and amends the Department's regulations accordingly.

**DATES:** This rule is effective October 1, 1997.

**ADDRESSES:** Chief, Legislation and Regulations Division, Visa Office, Room L603-C, SA-1, Washington, D.C. 20520-0106.

**FOR FURTHER INFORMATION CONTACT:** Stephen K. Fischel, Chief, Legislation