

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**
**Food and Drug Administration**
**21 CFR Part 178**
**[Docket No. 84F-0300]**
**Indirect Food Additives: Adjuvants,  
Production Aids, and Sanitizers**
*Correction*

In FR Doc. 85-12290 beginning on page 21041 in the issue of Wednesday, May 22, 1985, under "FOR FURTHER INFORMATION CONTACT", the telephone number was inadvertently omitted and should be inserted after the zip code to read, "202-472-5690".

**BILLING CODE 1505-01-M**
**21 CFR Part 510**
**Penicillin Antibiotic Drugs for Animal  
Use; Change of Sponsor**
*Correction*

In FR Doc. 85-12288 beginning on page 21045 in the issue of Wednesday, May 22, 1985, in the third column, in the tables contained in § 510.600(c) (1) and (2), the firm name "West Argo, Inc.," should read "West Agro, Inc.,"

**BILLING CODE 1505-01-M**
**DEPARTMENT OF JUSTICE**
**Drug Enforcement Administration**
**21 CFR Part 1303**
**Schedules of Controlled Substances;  
Temporary Placement of 3,4-  
Methylenedioxyamphetamine  
(MDMA) Into Schedule I**
**AGENCY:** Drug Enforcement  
Administration, Justice.

**ACTION:** Final rule.

**SUMMARY:** The Acting Administrator of the Drug Enforcement Administration (DEA) is issuing this notice to temporarily place 3,4-methylenedioxyamphetamine (MDMA) into Schedule I of the Controlled Substances Act (CSA) pursuant to the emergency scheduling provisions of the CSA. This action is based on a finding that the scheduling of MDMA in Schedule I is necessary to avoid an imminent hazard to the public safety. This action will impose the criminal sanctions and regulatory controls of Schedule I on the

manufacture, distribution and possession of MDMA.

**EFFECTIVE DATE:** On July 1, 1985, MDMA will be subject to Schedule I control.

**FOR FURTHER INFORMATION CONTACT:** Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, D.C. 20537.

**SUPPLEMENTARY INFORMATION:**
**List of Subjects in 21 CFR Part 1308**

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

The Comprehensive Crime Control Act of 1984 (Pub. L. 98-473) which was signed into law on October 12, 1984, amended section 201 of the CSA (21 U.S.C. 811) to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA if he finds that such action is necessary to avoid an imminent hazard to the public safety. A substance may be scheduled under the emergency provisions of the CSA if that substance is not listed in any other schedule under section 202 of the CSA (21 U.S.C. 812) or if there is no approval or exemption in effect under 21 U.S.C. 355 for the substance. The Attorney General has delegated his authority under 21 U.S.C. 811 to the Acting Administrator of the Drug Enforcement Administration (28 CFR 0.100(b)).

As required by section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)), the Acting Administrator has notified the Secretary of Health and Human Services of his intention to place MDMA into Schedule I pursuant to the emergency scheduling provisions. Such action may not take effect until the expiration of thirty days after notification is transmitted to the Secretary.

In making a finding of an imminent hazard to the public safety, the Attorney General is required to consider only those factors set forth in paragraphs (4) the history and current pattern of abuse, (5) the scope, duration and significance of abuse, and (6) what, if any, risk there is to the public health, of section 201(c) of the CSA (21 U.S.C. 811(c)).

House Report 98-835 which accompanied Pub. L. 98-473 states that "This new procedure (emergency scheduling) is intended by the Committee to apply to what has been called 'designer drugs,' new chemical analogs or variations of existing controlled substances, or other new substances, which have a psychedelic, stimulant or depressant effect and have a high potential for abuse." The report further states that this provision may apply to "substances which have been

known to chemists for some time, (which) are 'discovered' by illicit drug researchers to have psychedelic effects." 3,4-Methylenedioxyamphetamine (MDMA) is such a so-called designer drug which can produce psychedelic effects and which Congress clearly intended to be considered for emergency scheduling.

On July 27, 1984, in a Federal Register notice (49 FR 30210-1), the Administrator of DEA proposed to place MDMA into Schedule I of the CSA pursuant to the traditional scheduling provisions of section 201(a) of the CSA (21 U.S.C. 811(a)). This proposal was based on a review by DEA which showed that: (1) MDMA is chemically and pharmacologically related to 3,4-methylenedioxyamphetamine (MDA), a schedule I controlled substance, (2) MDMA has no legitimate medical use or manufacturer in the United States, (3) MDMA is produced in clandestine laboratories and encountered in the illicit drug traffic, and that (4) MDMA has been associated with medical emergencies as reported by the Drug Abuse Warning Network (DAWN) and drug abuse treatment programs, and on a scientific and medical evaluation and scheduling recommendation for MDMA by the Department of Health and Human Services which found that MDMA has a high potential for abuse, that MDMA presents a significant risk of harm to the public health, and that MDMA should be placed into Schedule I of the CSA. This information supported the findings of the DEA Administrator, as published in the July 27, 1985 Federal Register notice, that (1) MDMA has a high potential for abuse, (2) MDMA has no currently accepted medical use in treatment in the United States, and (3) there is a lack of accepted safety for the use of MDMA under medical supervision. As described in section 202(b)(1) of the CSA (21 U.S.C. 812(b)(1)), these findings for MDMA are consistent with its Schedule I control under the CSA.

Several interested individuals have requested a hearing in this matter following the publication of the Federal Register notice. On December 31, 1984, in a Federal Register notice (49 FR 50732-3), the DEA Administrator announced that a hearing would be convened before Administrative Law Judge Francis L. Young regarding the scheduling of MDMA. The hearing process is currently underway but the schedule suggests that this rulemaking process will not be completed before the end of 1985.

DEA has continued to gather information concerning the abuse of MDMA since the initial proposal to control it was published. Notwithstanding the above proceeding, information has come to light which clearly shows that placing MDMA into Schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety. Unapproved, so-called therapeutic use of MDMA as well as unregulated and uncontrolled production of MDMA continues in many sections of the country. Clandestine production, distribution and abuse of MDMA is occurring nationwide and appears to be escalating. The open promotion of MDMA as a legal euphoriant through fliers, circulars and promotional parties has recently surfaced in some areas. DEA agents estimate that 30,000 dosage units of MDMA are distributed each month in one Texas city. Drug abuse treatment programs have reported that they are seeing individuals seeking treatment who have taken multiple doses of MDMA. Additionally, DEA has been informed, that in April, 1985, the 22nd Expert Committee on Drug Dependence of the World Health Organization (WHO) recommended that MDMA be controlled in Schedule I of the Convention on Psychotropic Substances, 1971.

Of immediate concern to DEA in terms of hazard to the public safety is a very recent research finding which suggests that MDMA has neurotoxic properties. A paper entitled "Hallucinogenic Amphetamine Selectively Destroys Brain Serotonin Nerve Terminals: Neurochemical and Anatomical Evidence" by G. Ricaurte, G. Bryan, L. Strauss, L. Seiden and C. Schuster, describes studies which show that single or multiple doses of MDA selectively destroy serotonergic nerve terminals in the rat brain. The serotonergic system which is also present in man plays a role in regulating sleep, mood, sexual activity and sensitivity to aversive stimuli. Experts have concluded that because of the neurotoxic effects of closely related structural analogs of MDMA (MDA, amphetamine and methamphetamine) and because both MDA and MDMA cause the release of endogenous serotonin, it is likely that MDMA will produce similar neurotoxic effects to those of MDA. Furthermore, the neurotoxicity of amphetamine and methamphetamine has been shown in 5 diverse mammalian species. This strongly suggests that the substances would be neurotoxic to humans.

In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, the Acting Administrator has considered the following factors described in section 201(c) of the CSA (21 U.S.C. 811(c)) relative to making a determination of whether MDMA poses an imminent hazard to the public safety:

(4) Its history and current pattern of abuse.

(5) The scope, duration, and significance of abuse.

(6) What, if any, risk there is to the public health.

Based on a consideration of these factors and in light of the continuing and apparently increasing number of people being exposed to MDMA, its potential neurotoxicity and the lack of accepted medical use or established safety for use of MDMA, the Acting Administrator, pursuant to section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, finds that scheduling MDMA in Schedule I of the CSA, at least on a temporary basis, is necessary to avoid an imminent hazard to the public safety.

The Acting Administrator has transmitted notice of his intention to temporarily place MDMA into Schedule I of the CSA to the Secretary of Health and Human Services. Comments submitted by the Secretary in response to the notification, including whether there is an exemption or approval in effect for MDMA under the Federal Food, Drug and Cosmetic Act, shall be taken into consideration by the Acting Administrator before the notice becomes effective.

Pursuant to the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, the Acting Administrator hereby orders that on July 1, 1985, MDMA (3,4-methylenedioxyamphetamine), its optical, positional and geometric isomers, salts and salts of isomers, be placed into Schedule I of the CSA (21 U.S.C. 801 et seq.) unless the Acting Administrator gives notice in the *Federal Register* that this order is rescinded prior to July 1, 1985.

#### PART 1308—[AMENDED]

For the reasons set forth above, 21 CFR 1308.11(g) is amended as follows:

1. The authority citation for 21 CFR Part 1308 is revised to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b).

2. Section 1308.11(g)(2) is added to read as follows:

§ 1308.11 Schedule I.

\* \* \* \* \*

(g) \* \* \*

(2) 3,4-methylenedioxyamphetamine (MDMA), its optical, positional and geometric isomers, salts and salts of isomers.....7405

\* \* \* \* \*

The temporary placement of MDMA into Schedule I pursuant to 21 U.S.C. 811(h) is a completely separate and parallel action from the proposed scheduling of MDMA pursuant to 21 U.S.C. 811(a). This action will in no way interfere with the hearing in progress regarding the permanent scheduling of MDMA. This temporary scheduling of MDMA in Schedule I pursuant to 21 U.S.C. 811(h) will expire at the end of one year from the date of this order unless the proceedings initiated pursuant to 21 U.S.C. 811(a) are still pending. In such case, the temporary scheduling of MDMA may be extended for up to six months.

All regulations and criminal sanctions applicable to Schedule I substances are effective on July 1, 1985, with respect to MDMA. However, individuals registered with DEA in accordance with Part 1301 or 1311 of Title 21 of the Code of Federal Regulations and who currently possess MDMA may continue to do so pending submission of an amended registration no later than July 30, 1985. Researchers registered in schedules other than Schedule I are required to obtain a separate registration for Schedule I research. In light of the current interest in research regarding MDMA, DEA will expedite the processing of all new Schedule I researcher applications and amendments to current Schedule I registrations. As described in 21 CFR 1301.32(a) and (b) and 1301.33, in order to conduct research with a controlled substance in Schedule I, a person must submit a research protocol for FDA approval, or in the case of clinical research, an Investigational New drug application (IND) for FDA approval. DEA will work closely with FDA in expeditiously processing all research protocols and IND applications for MDMA submitted in compliance with appropriate regulations. IND applications must contain information concerning the chemistry and manufacture of MDMA, its toxic profile in animals and detailed protocols regarding the clinical studies to be conducted.

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports MDMA, or who engages in research or conducts instructional activities with respect to this substance, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with Parts 1301 and 1311 of

Title 21 of the Code of Federal Regulations.

2. *Security.* MDMA must be manufactured, distributed and stored in accordance with §§ 1301.71-1301.76 of Title 21 of the Code of Federal Regulations.

3. *Labeling and Packaging.* All labels and labeling for commercial containers of MDMA must comply with the requirements of §§ 1302.03-1302.05, 1302.07 and 1302.08 of Title 21 of the Code of Federal Regulations.

4. *Quotas.* All persons required to obtain quotas for MDMA shall submit applications pursuant to §§ 1303.12 and 1303.22 of Title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of MDMA shall take an inventory pursuant to §§ 1304.11-1304.19 of Title 21 of the Code of Federal Regulations of all stocks of this substance on hand.

6. *Records.* All registrants required to keep records pursuant to §§ 1304.21-1304.27 of Title 21 of the Code of Federal Regulations shall do so regarding MDMA.

7. *Reports.* All registrants required to submit reports pursuant to §§ 1304.37-1304.41 of Title 21 of the Code of Federal Regulations shall do so regarding MDMA.

8. *Order Forms.* All registrants involved in distribution of MDMA shall comply with the order form requirements of § 1305.01-1305.16 of Title 21 of the Code of Federal Regulations.

9. *Importation and Exportation.* All importation and exportation of MDMA shall be in compliance with Part 1312 of Title 21 of the Code of Federal Regulations.

10. *Criminal Liability.* Any activity with respect to MDMA not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring after July 1, 1985, is unlawful.

Pursuant to 5 U.S.C. 605(b), the Acting administrator certifies that the temporary placement of MDMA into Schedule I of the Controlled Substances Act will have no impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). This action involves the temporary control of a substance with no currently approved medical use or manufacture in the United States.

It has been determined that the temporary placement of MDMA in Schedule I of the CSA under the emergency scheduling provisions is a

statutory exception to the requirements of Executive Order 12291 (46 FR 13193).

Dated: May 28, 1985.

John C. Lawn,  
Acting Administrator, Drug Enforcement  
Administration.

[FR Doc. 85-13171 Filed 5-30-85; 8:45 am]  
BILLING CODE 4410-09-M

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### 32 CFR Part 199

[DoD Regulation 6010.8-R, Amdt. No. 27]

#### Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Modification of Nonavailability Statement Requirement When the Beneficiary Has Primary Coverage Provided by Another Insurance Plan or Program

**AGENCY:** Office of the Secretary, DoD.

**ACTION:** Amendment to final rule.

**SUMMARY:** This amendment to final rule revises the comprehensive CHAMPUS Regulation, DoD 6010.8-R (32 CFR Part 199), pertaining to the requirement for nonavailability statements. This amendment provides an exception to the requirement in all cases where the beneficiary has primary coverage provided by another insurance plan or program.

**DATES:** This amendment is effective for all claims processed on or after October 12, 1984—the date Pub. L. 98-473 was signed into effect. Comments will be accepted until July 1, 1985.

**ADDRESSES:** Send comments to, Stephen E. Isaacson, Policy Branch, OCHAMPUS, Aurora, Colorado, 80045.

**FOR FURTHER INFORMATION CONTACT:** Stephen E. Isaacson, Policy Branch, OCHAMPUS, telephone (303) 361-4005.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 77-7834, appearing in the *Federal Register* on April 4, 1977, (42 FR 17972), the Office of the Secretary of Defense published its regulation, DoD 6010.8-R, "Implementation of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)," as Part 199 of this title.

Currently, a nonavailability statement is required in order for CHAMPUS to pay for nonemergency inpatient hospital care whenever the beneficiary lives within specified ZIP Code areas around a Uniformed Services Medical Treatment Facility. The only exception to this requirement is that a nonavailability statement is not required if the beneficiary has other insurance

which pays for at least 75 percent of the covered services.

Section 8031 of Pub. L. 98-473 modifies this exception. Under this change, a nonavailability statement is not required if the beneficiary has coverage provided by another insurance plan or program which is primary payer. The only insurance plans or programs which are not primary to CHAMPUS are: (1) Plans administered under title XIX of the Social Security Act (Medicaid); (2) coverage specifically designed to supplement CHAMPUS benefits; and (3) certain federal government programs, as prescribed by the Director, OCHAMPUS, which are designed to provide benefits to a distinct beneficiary population and for which entitlement does not derive from either premium payment or monetary contribution.

This change will greatly simplify the beneficiary's task of determining if a nonavailability statement is required. Previously, in order to determine if a nonavailability statement was required, the beneficiary had to make the often difficult decision, prior to receiving any services, as to whether the other insurance eventually would pay for 75% of the covered services. Because of cost-sharing amounts, deductibles, and various non-covered services this often proved to be nearly impossible. Under this current change, the beneficiary's decision need be based only on whether the other insurance is primary payer regardless of the actual amounts eventually paid by the other insurance plan or program.

As authorized under 32 CFR 296.2(d)(4), the final regulation is being published and no previous public comment has been requested. This change is authorized through Pub. L. 98-473 which was effective October 12, 1984. Therefore, we do not believe it is in the public interest to delay the implementation through the publication of a proposed rule. However, for a period of 30 days following the date of the publication of this amendment in the *Federal Register*, we will accept public comments and, where appropriate, will revise the amendment. A notice advising of any revisions resulting from public comments will be published in the *Federal Register* no later than 90 days following the end of the comment period. Written public comments must be received on or before July 1, 1985.

Section 605(b) of the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires that each federal agency prepare, and make available for public comment, a regulatory flexibility analysis when the agency issues regulations which would have a