period for filing briefs opposing exceptions.

Wisconsin Customers argue that the final rule penalizes participants not represented by counsel in Washington, D.C. because of the time involved, first, in obtaining a copy of the brief on exceptions; and, second, in preparing a brief opposing exceptions with sufficient speed to permit its filing within 10 days. By their calculations, a non-Washington attorney would effectively have only four days in which to prepare a brief to the Commission opposing exceptions. They therefore suggest that the time periods for briefs on the opposing exceptions should each be extended by 10 days to 30 and 20 days, respectively. They contend that this additional time will have a negligible effect on "speeding up the regulatory process" and will allow them to draft a brief "in a coherent and well-reasoned fashion."

Wisconsin Customer's further argue that because the Commission will rely on these briefs for its final decision, their preparation "should not be regarded in any sense as perfunctory by the parties or the Commission."

C. Disposition

The Commission is not persuaded to change the procedural timetables established in the final rule for several reasons. First, as a general proposition, although the Commission recognizes that its rule could require an effort to comply on the part of some participants, the Commission believes that the need to expedite its proceedings far outweighs any drawbacks of the time limits established in the final rule. The overall goal of the final rule is to accelerate the Commission's decision-making process in certain electric rate cases, which will benefit all parties involved. The prejudice to all participants occasioned by unnecessary delays in these proceedings, which the rule is designed to avert, sufficiently justifies keeping the current time limits even though some participants will have to prepare briefs within short time periods.

Second, in establishing procedures, the Commission does, of course, take into account the needs of all entities likely to be affected. In the final rule at issue here, the Commission revised its procedural timetables to account for the concerns expressed by commenters to the Notice of Proposed Rulemaking. Because the Commission's goal is to promulgate uniform rules that will meet its general policy objectives equitably, we are not now persuaded to depart from the timetables in the final rule. Third, the rehearing request from Wisconsin Customers focuses primarily on the 10-day time limit for briefs opposing exceptions and contains no basis for modifying the 20-day period permitted for briefs on exceptions.

We do not agree with the Wisconsin Customers that the time limit is insufficient. We believe that there is no need for the 20-day period, as the time allotted to the Wisconsin Customers for them to file their brief opposing exceptions is not unreasonable. Therefore, we do not agree with their request.

Fourth, technological improvements in communications, as well as the availability of numerous overnight delivery services, should speed up the actual transit time needed to obtain or file briefs. These factors further convince the Commission that its original determination is correct and that expedient processing of issues is preferable.

The Commission appreciates the importance of these briefs but believes that, in most cases, the briefs will address issues that have been aired throughout the proceeding or, at a minimum, during reconsideration. As a result, participants generally will have had ample opportunity to formulate their own views and will be able to draft their briefs opposing exception quickly.

III. Conclusion

For the foregoing reasons, the Commission deems rehearing of the final rule as requested by Wisconsin Customers.

By the Commission.

Kenneth F. Plumb,
Secretary.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Rescheduling of Methaqualone From Schedule II to Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This is a final rule issued by the Administrator of the Drug Enforcement Administration (DEA) rescheduling the Schedule II depressant methaqualone into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). This action is required in order to implement Pub. L. 98-329, an Act to provide for the rescheduling of methaqualone into Schedule I of the CSA and for the withdrawal of approval of its new drug application.


FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, D.C., 20537, Telephone: (202) 632-1366.

SUPPLEMENTARY INFORMATION: On June 29, 1994, Pub. L. 98-329 was enacted, thereby requiring the Attorney General to transfer methaqualone from Schedule II to Schedule I of the CSA. Pub. L. 98-329 also requires the Secretary of the Department of Health and Human Services (DHHS), pursuant to section 505 of the Federal Food, Drug and Cosmetic Act, to withdraw the approval of the new drug application for methaqualone. After the rescheduling and the withdrawal of approval of the new drug application, methaqualone will no longer be available for prescription by medical practitioners or dispensing by pharmacists. Persons currently registered with DEA to conduct Schedule II activities with methaqualone will not be allowed to conduct such activities after [August 27, 1994], except as otherwise provided in paragraphs 2 and 4 below. Persons interested in conducting activities allowed for Schedule I substances must comply with the following:

1. Registration. Any person not currently registered for Schedule I activities who manufactures, distributes, imports, exports, engages in research, or conducts instructional activities with respect to methaqualone, or who proposes to engage in such activities, shall submit an application for Schedule I registration to conduct such activities in accordance with 21 CFR Parts 1301 and 1311.

2. Disposal of Stock. Any person who elects not to obtain a Schedule I registration or is not entitled to such registration must surrender all quantities of currently held methaqualone in accordance with procedures outlined in 21 CFR 1307.21 on or before [October 20, 1994]. All surrendered methaqualone must be listed on a DEA Form 41,
"Inventory of Controlled Substances Surrendered for Destruction." DEA Form 41 and the nearest instructions can be obtained from the DEA office. In accordance with 21 CFR 1307.21(b)(3), pharmacy stocks of methaqualone may be disposed of by state pharmacy board inspectors.

3. Security. Methaqualone must be manufactured, distributed and stored in accordance with 21 CFR 1301.71-1301.76.

4. Labeling and Packaging. All labels and labeling for commercial containers of methaqualone, packaged after October 26, 1984, shall comply with the requirements of 21 CFR 1302.05-1302.05 and 1302.07-1302.08. In the event that this effective date imposes special hardships on any "manufacturer", as defined in section 102(14) of the CSA (21 U.S.C. 802(14)), the Drug Enforcement Administration will entertain any justified requests for extensions of time submitted to it on or before the required date of compliance.

5. Quotas. All persons required to obtain quotas for methaqualone shall submit applications pursuant to 21 CFR 1303.12 and 1303.22.

6. Inventory. Every registrant required to keep records, who possesses any quantity of methaqualone, shall maintain an inventory, pursuant to 21 CFR 1304.11-1304.19, of all stocks of methaqualone. Every registrant who desires registration in Schedule I shall conduct of inventory of all stocks of methaqualone on or before [October 26, 1984.]

7. Records. All registrants required to keep records pursuant to 21 CFR 1304.21-1304.27 shall maintain such records on methaqualone commencing on or before [October 26, 1984.]

8. Reports. All registrants required to submit reports on methaqualone to the Drug Enforcement Administration pursuant to 21 CFR 1304.37-1304.41 shall report on the inventory taken under paragraph 6 above and on all subsequent transactions.


10. Importation and Exportation. All importation and exportation of methaqualone shall be in compliance with 21 CFR Part 1312.

11. Criminal Liability. The Administrator, Drug Enforcement Administration, hereby orders that any activity with respect to methaqualone not authorized by, or in violation of the, CSA or the Controlled Substances Import and Export Act, shall continue to be unlawful.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the placement of methaqualone into Schedule I of the CSA 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 transfer to Schedule I of methaqualone which is no longer manufactured for marketing as a prescription drug. This action is mandated by law and is to be followed by withdrawal of approval of the new drug application for methaqualone.

In accordance with the provisions of 21 U.S.C. 812(d)(1), this scheduling action is a formal rulemaking that is required by Pub. L. 98-329. Such formal proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557, and as such, have been exempted from the consultation requirements of Executive Order 12291 (46 FR 19193).

List of Subjects in 21 CFR Part 1308

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

PART 1308—[AMENDED]

Therefore, under the authority vested in the Attorney General by § 201(g)(1) of the CSA (21 U.S.C. § 812(g)) and Pub. L. 98-329 and delegated to the Administrator of the Drug Enforcement Administration pursuant to 28 CFR § 100.2, the Administrator hereby orders that 21 CFR Part 1308 be amended:

§ 1308.12 [Amended]

1. By removing Methaqualone as item (2) of § 1308.12(e) and renumbering items (3) Pentobarbital, (4) Phencyclidine and (5) Secobarbital as items (2), (3) and (4), respectively, and;
2. By amending paragraph (e) of § 1308.11 to include methaqualone as item (2) to read as follows:

§ 1308.11 Schedule I

(1) Methaqualone
(2) Methaqualone

Dated: August 17, 1984.
Francis M. Mullen, Jr.
Administrator, Drug Enforcement Administration.