(2) A statement that the product shall not be rehydrated until immediately prior to use.

(3) For final containers intended for multiple tests, a statement identifying the period within which the product in multiple test containers may be used after reconstitution.

(4) For final containers intended for multiple tests, a statement specifying storage conditions after reconstitution.

(c) *Package insert.* The package insert shall include the following:

(1) A statement that the diluent used to rehydrate the lysate must be tested, without addition of the test material, in parallel with the test material.

(2) A warning statement that the tubes of material on test should not be removed from incubation or disturbed prior to the time specified for reading the test.

(3) A statement that the product shall not be rehydrated until immediately prior to use.

(4) For final containers intended for multiple tests, a statement identifying the period within which the product may be used after reconstitution.

(5) For final containers intended for multiple tests, an appropriate statement specifying storage conditions after reconstitution.

§ 660.105 Samples; protocols; official release.

For each final filling of each lot of Limulus Amebocyte Lysate, the following material shall be submitted to the Director, Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, Md. 20014:

(a) *Samples.* Not less than 28 vials of lysate, 3 of which shall be complete market packages, packaged for distribution and including all ancillary reagents and materials.

(b) *Protocols.* A protocol consisting of a complete summary of the history of manufacture of each filling, the dates of testing, and the results of all tests that are required by regulations.

(c) *Official release.* Limulus Amebocyte Lysate shall not be distributed by the manufacturer until written notification of official release of each filling is received from the Director, Bureau of Biologics.

Interested persons may, on or before October 10, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

NOTE.—The Food and Drug Administration has determined that this proposal will not have a major economic impact as defined by Executive Order 11821 (amended by Executive Order 11949) and OMB Circular A-107. A copy of the economic impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: July 27, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-22169 Filed 8-10-78; 8:45 am]

[4410-09]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Part 1308]

SCHEDULES OF CONTROLLED SUBSTANCES

Proposed placement of N-ethyl-1-phenylcyclohexylamine and 1-(1-phenylcyclohexyl)pyrrolidien into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This is a notice of proposed rulemaking issued by the Administrator of the Drug Enforcement Administration to place two analogs of the drug phencyclidine (PCP) into schedule I of the Controlled Substances Act. This action was initiated upon receipt of a letter from the Assistant Secretary for Health, on behalf of the Secretary of the Department of Health, Education, and Welfare which recommended that PCE, which is N-ethyl-1-phenylcyclohexylamine and PHP, which is 1-(1-phenylcyclohexyl)pyrrolidine be placed into schedule I of the Act. The effect of the present proposal would be to provide regulatory controls upon the manufacture, distribution, dispensing, importation and exportation of these substances.

DATES: Comments and objections should be received on or before September 11, 1978.

ADDRESS: Send comments and objections in quintuplicate to: Administrator, Drug Enforcement Administration, U.S. Department of Justice, 1405 I Street NW., Washington, D.C. 20537. Attention: DEA Federal Representative.

FOR FURTHER INFORMATION CONTACT:

Howard McClain, Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, telephone 202-633-1366.

SUPPLEMENTARY INFORMATION: The Assistant Secretary for Health, Department of Health, Education, and Welfare sent a letter dated August 7, 1978, with supportive information to the Administrator of the Drug Enforcement Administration which recommended that two analogs of phencyclidine, i.e. N-ethyl-1-phenylcyclohexylamine, which is PCE, and 1-(1-phenylcyclohexyl)pyrrolidine, which is PHP, be placed into schedule I of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801-966). The letter and the conclusions of the Assistant Secretary are set forth below:

Mr. PETER N. BENSINGER,
Administrator, Drug Enforcement Administration, Washington, D.C. 20537.

DEAR MR. BENSINGER: On December 8, 1977, we addressed a letter to your office recommending phencyclidine (PCP) be moved from schedule III to schedule II of the Controlled Substances Act. That letter stated that your staff was gathering data pursuant to the control of analogs of phencyclidine which may have abuse potential similar to phencyclidine. Your staff has gathered data concerning the PCP analogs PCE (1-phenylcyclohexylethylamine) and PHP (1-(1-phenylcyclohexyl-pyrrolidine)), and transmitted such data to HEW. The staff at HEW has reviewed the information and concluded that PCE and PHP are substances which have a high potential for abuse; that these substances have no currently accepted medical use in treatment in the United States; and that these substances lack accepted safety for use under medical supervision in the United States. The basis upon which these conclusions were made is included as an enclosure with this letter.

Because PCE and PHP represent a potentially significant risk to the public health and meet the criteria for control under schedule I of the Controlled Substances Act, I recommend that PCE and PHP be controlled under schedule I of the Controlled Substances Act.

Sincerely yours,

JULIUS B. RICHARD, M.D.
Assistant Secretary for Health and Surgeon General.

Enclosure.

The Drug Enforcement Administration has concluded a review of N-ethyl-1-phenylcyclohexylamine and 1-(1-phenylcyclohexyl)pyrrolidine which has included the following:

1. Published scientific and medical literature from the United States and other nations regarding these substances;

2. Materials on file with the Drug Enforcement Administration and those provided by the Assistant Secretary;

3. The legislative history of the Controlled Substances Act.

Based upon the investigations and review of the Drug Enforcement Administration and upon the scientific

and medical evaluation and recommendation submitted in behalf of the Secretary of Health, Education, and Welfare, received pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), the Administrator of the Drug Enforcement Administration finds that:

1. Based on the information now available N-ethyl-1-phenylcyclo-hexylamine ("PCE") and 1-(1-phenylcyclohexyl)pyrrolidine ("PHP") each have a high potential for abuse;

2. Neither substance has a currently accepted medical use in treatment in the United States;

3. N-ethyl-1-phenylcyclohexylamine ("PCE") and 1-(1-phenylcyclohexyl)pyrrolidine ("PHP") each lacks accepted safety for use under medical supervision.

Therefore, under the authority vested in him by the Act and by regulations of the Department of Justice, the Administrator of the Drug Enforcement Administration hereby proposes that §1308.11(d) of Title 21 of the Code of Federal Regulations (CFR) be amended to read as follows:

§1306.11 Schedule I.

* * * * *

(d) *Hallucinogens*

* * * * *

(21) N-ethyl analog of phencyclidine—7445. Some trade or other names: N-ethyl-1-phenylcyclohexylamine (1-phenylcyclohexyl)ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE.

(22) Pyrrolidine analog of phencyclidine—7458. Some trade or other names: 1-(1-phenylcyclohexyl)pyrrolidine, PCPy, PHP.

(23) Thiophene analog of phencyclidine—7470. Some trade of other names: 1-[1-(2-thienyl)cyclohexyl]piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP.

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All interested persons are invited to submit their comments or objections in writing regarding this proposal. These comments or objections should state with particularity the issues to be heard. All such submissions must be received on or before September 11, 1978.

In the event that an interested party submits objections to these proposals which present reasonable grounds for these rules not to be finalized and requests a hearing in accordance with 21 CFR 1308.45, the party will be notified by registered mail of the time and place that the hearing will be held. If any objections which are submitted do not present reasonable grounds, the party will be so advised by registered mail.

If no objections presenting grounds for a hearing on these proposals are received within the time limitations, or all interested parties waive or are deemed to waive their opportunity for a hearing or to participate in a hearing, the Administrator, after giving consideration to written comments and objections, will issue his final order pursuant to 21 CFR 1308.48 without a hearing.

Dated: August 9, 1978.

PETER B. BENSINGER,
Administrator,
Drug Enforcement Administration.

[FR Doc. 78-22639 Filed 8-10-78; 8:45 am]

[4830-01]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[26 CFR Part 1]

[LR-136-76]

INCOME TAX

Contributions in Aid of Construction for Certain Utilities: Public Hearing on Proposed Regulations

AGENCY: Internal Revenue Service, Treasury.

ACTION: Public Hearing on proposed regulations.

SUMMARY: This document provides notice of a public hearing on proposed regulations relating to contributions in aid of construction for certain utilities.

DATES: The public hearing will be held on September 27, 1978, beginning at 10 a.m. Outlines of oral comments must be delivered or mailed by September 11, 1978.

ADDRESS: The public hearing will be held in the I.R.S. Auditorium, Seventh Floor, 7400 Corridor, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, D.C. The outlines should be submitted to the Commissioner of Internal Revenue, Attn: CC:LR:T (LR-136-76), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT:

George Bradley or Charles Hayden of the Legislation and Regulations Division, Office of Chief Counsel, Internal Service, 1111 Constitution Avenue NW., Washington, D.C. 20224, 202-566-3935, not a toll-free call.

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations under section 118(b) of the Internal Revenue Code of 1954. The proposed regulations appeared in the FEDERAL REGISTER for Tuesday, May 30, 1978, at page 22997 (43 FR 22997).

The rules of §601.601(a)(3) of the "Statement of Procedural Rules" (26 CFR Part 601) shall apply with respect to the public hearing. Persons who have submitted written comments within the time prescribed in the notice of proposed rulemaking and also desire to present oral comments at the hearing on the proposed regulations should submit an outline of the comments to be presented at the hearing and the time they wish to devote to each subject by September 11, 1978. Each speaker will be limited to 10 minutes for an oral presentation exclusive of time consumed by questions from the panel for the Government and answers to these questions.

Because of controlled access restriction, attendees cannot be admitted beyond the lobby of the Internal Revenue Building until 9:45 a.m.

An agenda showing the scheduling of the speakers will be made after outlines are received from the speakers. Copies of the agenda will be available free of charge at the hearing.

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the proposed Treasury Directive appearing in the FEDERAL REGISTER for Wednesday, May 24, 1978.

By direction of the Commissioner of Internal Revenue.

ROBERT A. BLEY,
Director,
Legislation and Regulations Division.

[FR Doc. 78-22469 Filed 8-10-78; 8:45 am]

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 120]

[FRL 944-2]

WATER QUALITY STANDARDS

Navigable Waters of the State of Mississippi Public Hearings

AGENCY: Environmental Protection Agency.

ACTION: Notice of public hearings.

SUMMARY: Public Hearings will be held in Jackson, Miss., and Biloxi, Miss., to receive comments on the Environmental Protection Agency's proposed rule establishing dissolved oxygen criteria for the navigable waters of Mississippi, previously announced in the FEDERAL REGISTER on July 13, 1978 (43 FR 30076).