PROPOSED RULES

(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 lysozyme 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 state-
ment specifying storage conditions after reconstitution.

§ 660.105 Samples; protocols; official
release.

For each final filling of each lot of Limulus Ameboocyte Lysate, the follow-
ing material shall be submitted to the Director, Bureau of Biologicals,
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 packets or bundles for distribution and including all ancillary re-
gents 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 Amebo-
cyte Lysate shall not be distributed by the manufacturer until written notifi-
cation of official release of each filling is received from the Director, Bureau
of Biologicals.

Interested persons may, on or before October 10, 1978, send to the Hear-
ing Clerk (CPA-303), Food and Drug Administration, Room 4-65, 5600 Fish-
ers Lane, Rockville, Md. 20857, written comments regarding this proposal.
Four copies of all comments shall be
submitted within which the comments are
submitted with the hearing clerk.

The Drug Enforcement Administra-
tion has concluded a review of N-
ethyl-1-phenylethoxylamine and 1-(1-
phenylethoxyl)pyrrolidine which has included the following:
1. Published scientific and medical
literature from the United States and
other nations regarding these sub-
stances;
2. Materials on file with the Drug
Enforcement Administration and
others provided by the Assistant Secre-
tary;
3. The legislative history of the Con-
trolled Substances Act.

Based upon the investigations and
review of the Drug Enforcement Ad-
motion and upon the scientific

[4410-09]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Part 1308]

SCHEDULES OF CONTROLLED SUBSTANCES

Proposed placement of N-ethyl-1-
phenylethoxylamine and 1-(1-
phenylethoxyl)pyrrolidine into Schedule I

AGENCY: Drug Enforcement Admin-
istration, Justice.

ACTION: Notice of proposed rule-
making.

SUMMARY: This is a notice of pro-
posed rulemaking issued by the Ad-
ministrator of the Drug Enforcement Admin-
istration to place two analogs of
the drug phenylcyclohexyline (PCP) into Schedule I of the Controlled Sub-
stances Act. This action was initiated
upon receipt of a letter from the As-

Assistant Secretary for Health, on behalf of the Secretary of
Health, Education, and Welfare which

The Assistant Secretary for Health, Education, and Welfare sent a letter dated August 7, 1978, with supportive information to the


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

[FR Doc. 78-22169 Filed 8-10-78; 8:45 am]
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)pyrroldine ("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)pyrroldine ("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:

§1308.11 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, cyclohexyl, PCE.

(22) Pyrroldidine analog of phencyclidine—7445. Some trade or other names: 1-(1-phenylcyclohexyl)pyrroldine, PCE, PHP.

(23) Thiophene analog of phencyclidine—7470. Some trade or other names: 1,1-(2-thienyl)cyclohexylpiperidin, 2-thienyl analog of phencyclidine, TCP, TPC.

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. 78-22539 Filed 8-10-78; 8:45 am)

[4830-01] DEPARTMENT OF THE TREASURY Internal Revenue Service
[26 CFR Part 1] (LR-130-76)

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-136-78), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT:


The rules of §601.601a(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 restrictions, attendees cannot be admitted beyond the lobby of the Internal Revenue Building until 8:45 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)

[6550-01] ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 120]

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).

FEDERAL REGISTER, VOL. 43, NO. 155—FRIDAY, AUGUST 11, 1978