particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:


2. New § 177.1345 is added to subpart B to read as follows:

§ 177.1345 Ethylene/1,3-phenylene oxoethylene isophthalate/terephthalate copolymer.

Ethylene/1,3-phenylene oxoethylene isophthalate/terephthalate copolymer (CAS Reg. No. 87365-96-8) may be safely used as the nonfood contact layer of laminated structures subject to the provisions of § 177.195 and this section:

(a) Identity. For the purpose of this section, ethylene/1,3-phenylene oxoethylene isophthalate/terephthalate copolymer consists of the basic copolymer produced by the catalytic polycondensation of isophthalic acid and terephthalic acid with ethylene glycol and 1,3-bis(2-hydroxyethoxy)benzene such that the finished resin contains between 42 and 48 mole-percent of isophthalic moieties, between 2 and 8 mole-percent of terephthalic moieties, and not more than 10 mole-percent of 1,3-bis(2-hydroxyethoxy)benzene moieties.

(b) Specifications—(1) Density. Ethylene/1,3-phenylene oxoethylene isophthalate/terephthalate copolymer identified in paragraph (a) of this section has a density of 1.33 ± 0.02 grams per cubic centimeter measured by ASTM Method D 1505-85 (Reapproved 1990), "Standard Test Method for Density of Plastics by the Density-Gradient Technique," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103, or may be examined at the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF-330), Food and Drug Administration, 500 C St. SW., Washington, DC 20204, and the Office of the Federal Register, 800 North Capitol, St. NW., suite 700, Washington, DC.

(2) Softening point. Ethylene/1,3-phenylene oxoethylene isophthalate/terephthalate copolymer identified in paragraph (a) of this section has a softening point of 63 ± 5 °C as measured by ASTM Method D 1525-87, "Standard Test Method for VICAT Softening Temperature of Plastics," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this material is provided in paragraph (b)(1) of this section.

(c) Optional adjuvant substances. Ethylene/1,3-phenylene oxoethylene isophthalate/terephthalate copolymer, identified in paragraph (a) of this section, may contain optional adjuvant substances required in their production. The optional adjuvants may include substances used in accordance with § 174.5 of this chapter.

3. Section 177.1395 is amended in the table in paragraph (b)(4) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

<table>
<thead>
<tr>
<th>Substances</th>
<th>Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethylene/1,3-phenylene oxoethylene isophthalate</td>
<td>For use only with polyethylene</td>
</tr>
<tr>
<td>lopolahthalate/terephthalate copolymer (CAS Reg.</td>
<td>lopolahthalate as the food-contact layer,</td>
</tr>
<tr>
<td>No. 87365-96-8) complying with § 177.1345</td>
<td>complying with § 177.1630 under conditions of use</td>
</tr>
<tr>
<td></td>
<td>C through G described in Table 2 of § 176.170(c)</td>
</tr>
<tr>
<td></td>
<td>of this chapter. Laminate structures, when</td>
</tr>
<tr>
<td></td>
<td>extracted with 6 percent ethanol at 150 °C for</td>
</tr>
<tr>
<td></td>
<td>2 hours shall not yield m-phenyl</td>
</tr>
<tr>
<td></td>
<td>1,3-dimethyl-2-dimethylphenyl-4-ethyl</td>
</tr>
<tr>
<td></td>
<td>isophthalamide or cyclic</td>
</tr>
<tr>
<td></td>
<td>bis(ethylene</td>
</tr>
<tr>
<td></td>
<td>isophthalamide in excess of 2.5 micrograms/</td>
</tr>
<tr>
<td></td>
<td>square inch of food-contact surface.</td>
</tr>
</tbody>
</table>

Dated: September 1, 1992.
Fred R. Shank,
Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-22474 Filed 9-18-92; 8:45 am]
BILLING CODE 4160-61-F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances
Temporary Placement of Aminorex
Into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to temporarily place aminorex 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 by the DEA Administrator that the scheduling of aminorex, at least on a temporary basis, is necessary to avoid an imminent hazard to the public safety. As a result of this rule, the regulatory controls and criminal sanctions imposed on Schedule I substances under the CSA will be applicable to the manufacture, distribution and possession of aminorex.

FOR FURTHER INFORMATION CONTACT:
Howard McClain, Jr., Chief, Drug and
Chemical Evaluation Section, Drug
Enforcement Administration,
Washington, DC 20537; Telephone: (202) 307-7183.

SUPPLEMENTARY INFORMATION:
The Comprehensive Crime Control Act of
1984 amended section 201 of the CSA (21
U.S.C. 811 et seq.) to give the Attorney
General the authority to temporarily place
a substance into Schedule I of the CSA if it is found that such action is
necessary to avoid an imminent hazard
to the public safety. The Attorney
General has delegated this authority
under 21 U.S.C. 811 to the Administrator
of the DEA (28 CFR 0.100). A substance
may be temporarily scheduled pursuant
to the emergency scheduling provisions
do not list in any schedule under Section 202 of the
CSA (21 U.S.C. 811) if there is no
approval or exemption in effect under 21
U.S.C. 355 of the Food, Drug and
Cosmetic Act of the substance.

A notice of intent to temporarily place
aminoxene into Schedule I of the CSA
was published in the Federal Register on
July 24, 1991 (57 FR 32937). The
Administrator transmitted notice of his
intention to temporarily place aminoxene
into Schedule I of the CSA to the
Assistant Secretary for Health of the
Department of Health and Human
Services. In response to this notification,
the Food and Drug Administration, by
letter, has advised DEA that there are
no exemptions or approvals in effect
under 21 U.S.C. 355 of the Food, Drug
and Cosmetic Act for aminoxene. The
letter further stated that the Department of
Health and Human Services has no
objections to DEA’s intention to
temporarily place aminoxene into
Schedule I of the CSA. No other
comments were received regarding this
matter.

Aminoxyen is a central nervous system
stimulant and is an analogue of drug
methylaminorex, which is a Schedule I
stimulant with a high potential for
abuse. Aminoxyen, also called
aminoxephen, 2-amino-5-phenyl-2-
oxazoline, or 4,5-dihydro-3-phenyl-2-
oxazolamine is a phenylethylamine in
which the side-chain has been cyclized
into a substituted oxazoline. Its
chemical structure is substantially
similar to that of drug-4-methylaminorex.
Available pharmacological data indicate
that aminoxyen produces amphetamine-
like, psychotomotor stimulant effects in
laboratory animals.

In accordance with 21 U.S.C. 811(h)(3),
the Administrator has considered the
following factors regarding aminoxyen: (1)
This final rule is not a major rule for the purposes of Executive Order (E.O.) 12291 (48 FR 13193) of February 17, 1983. It has been determined that drug scheduling matters are not subject to review by the Office of Management and Budget (OMB) pursuant to the provisions of E.O. 12291. Accordingly, this emergency scheduling action is not subject to the provisions of E.O. 12778 which are contingent upon review by OMB. This regulation both responds to an emergency situation posing an imminent danger to the public health and safety, and is essential to a criminal law enforcement function of the United States. Accordingly, it is not subject to the 90-day moratorium on regulations ordered by the President of the United States in his memorandum of January 28, 1992.

This action has been analyzed in accordance with the principles and criteria in E.O. 12862, and it has been determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

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

Under the authority vested in the Attorney General by Section 201(h) of the CSA (21 U.S.C. 811(h)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.190), the Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

§ 1308.11 Schedule I.

(g) Aminorex (Some other names: aminoxphen, 2-amino-5-phenyl-2-oxazoline, or 4,5-dihydro-5-phenyl-2-oxazolamine, its salts, optical isomers, and salts of optical isomers—1585.)

Robert C. Bonner, Administrator of Drug Enforcement.

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