on the United States securities exchanges, NASDAQ securities, and certain other OTC securities where the broker-dealer can demonstrate that there are independent market makers for the security who quote the securities in an inter-dealer network. With respect to foreign securities, in December 1975, the Division of Market Regulation ("Division") issued an interpretive letter deeming a "ready market" to exist in certain circumstances. Specifically, as described in that letter, only foreign equity securities that were publicly issued in a principal securities market and were listed on one of the principal exchanges in the major money markets outside the United States were deemed to have ready markets and receive haircuts similar to comparable United States securities traded on United States markets. The 12 exchanges in 11 countries which the Division recognized as being "principal exchanges in the major money markets" are: Amsterdam, Brussels, Frankfurt, Johannesburg, London, Luxembourg, Montreal, Paris, Sydney, Tokyo, Toronto, and Zurich.

II. Concerns With the 1975 Approach

The Securities Industry Association ("SIA") has reported that the Commission adopt the FT–Actuaries World Indexes ("FT–A World Indexes") as a ready market test for foreign equity securities. The SIA believes this treatment will more accurately reflect the liquidity of foreign securities in today's markets. The SIA suggests that the Division's current ready market interpretation could hinder U.S. broker-dealers in the global marketplace for securities.

The FT–Actuaries World Indexes are indices on exchanges from 24 countries and are jointly compiled by The Financial Times Limited, Goldman, Sachs & Co. and County NatWest/Wood Mackenzie (together the "Consortium") in conjunction with The Institute of Actuaries and the Faculty of Actuaries.

The Consortium generally attempts to include the largest, most liquid exchanges in its indexes so long as they meet certain standards for data dissemination and international interest. In determining which issues to include from a particular exchange, the Consortium subjects the issues listed on the exchange to five tests to screen out any small capitalization, high bid, or restricted ownership stock. The Consortium also considers the economic sectoral makeup of a market before determining which individual stocks to include.

In an earlier letter, the Capital Committee of the SIA stated that "the interpretation of 'ready market' contained in the 1975 letter...no longer accurately assesses the liquidity of foreign securities and results, in some cases, in onerous haircuts on securities that trade in what are in fact demonstrably liquid markets." The Capital Committee argued that since 1975 "new foreign securities markets have been established and the volume of trading in foreign securities by U.S. broker-dealers has increased significantly.

An objective approach that recognizes the most liquid individual securities from a large number of markets may be preferable to recognizing the stocks listed on particular exchanges in total for a number of reasons. First, the process of recognizing ready markets can raise sensitive perception concerns for foreign markets. The use of an objective approach which recognizes some securities from virtually all developed markets would solve most of these concerns. It would, in the case of the SIA proposal, shift responsibility to a credible group which compiles a widely followed index. Moreover, it would avoid the difficulties inherent in a case-by-case determination by the Commission of ready market status; reliance would be placed on the objective determination of the index compilers. Second, the objective approach would eliminate the incongruity of giving capital value to illiquid securities listed on a recognized exchange while giving no value to world class securities which are traded on exchanges not now recognized.

III. Questions for Comment

The Commission seeks comment on whether it would be advisable for the Commission to recognize privately prepared indexes for ready market purposes. The Commission also seeks comment on whether the advantage of having a system under which the most liquid securities generally are considered to be readily marketable outweighs problems that may arise from the Commission adopting this role. Finally, the Commission seeks recommendations on alternative approaches.

By the Commission

Dated: August 16, 1993
Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 93–20140 Filed 8–19–93; 8:45 am]
BILLING CODE 4170–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances; Proposed Placement of Aminorex Into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice of proposed rulemaking is issued by the Administrator of the Drug Enforcement Administration (DEA) to place aminorex into Schedule I of the Controlled Substances Act (CSA). This proposed action by the DEA Administrator is based on data gathered and reviewed by the DEA. If finalized, this proposed action would impose the regulatory control mechanisms and criminal
sanctions of Schedule I on the manufacture, distribution, and possession of aminorex.

DATES: Comments must be submitted on or before September 20, 1993

ADDRESSES: Comments and objections should be submitted to the Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative

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: On September 21, 1992, the Administrator of the DEA published a final rule in the Federal Register (57 FR 43399) amending §1308.11(g) of title 21 of the Code of Federal Regulations to temporarily place aminorex into Schedule I of the CSA pursuant to the temporary scheduling provisions of 21 U.S.C. 811(b). This final rule, which became effective on the date of publication, was based on findings by the Administrator that the temporary scheduling of aminorex was necessary to avoid an imminent hazard to the public safety. Section 201(h)(2) of the CSA (21 U.S.C. 811(h)(2)) requires that the temporary scheduling of a substance expires at the end of one year from the effective date of the order. However, if proceedings to schedule a substance pursuant to 21 U.S.C. 811(a)(1) have been initiated and are pending, the temporary scheduling of a substance may be extended for up to six months. Under this provision, the temporary scheduling of aminorex which would expire on September 21, 1993, may be extended to March 21, 1994. This extension is being ordered by the DEA Administrator in a separate action.

The DEA has gathered and reviewed the available information regarding the actual abuse and the relative potential for abuse of aminorex. The DEA, in conjunction with the National Institute on Drug Abuse (NIDA), has provided for the synthesis and biological testing of aminorex. The Administrator has submitted data which the DEA has gathered regarding aminorex to the Assistant Secretary for Health, Department of Health and Human Services. In accordance with 21 U.S.C. 811(b), the Administrator also requested a scientific and medical evaluation and a scheduling recommendation for aminorex from the Assistant Secretary for Health.

Aminorex, also called aminoxaphen, 2-amino-5-phenyl-2-oxazoline, or 4,5-dihydro-5-phenyl-2-oxazolamine, is a phenethylamine in which the side chain has been cyclized into a substituted oxazoline. In the mid 1960's, it was marketed as an anorectic agent in Austria, West Germany, and Switzerland but was withdrawn from the European market when it became apparent that aminorex administration was associated with a high risk of fatal pulmonary hypertension. The Food and Drug Administration (FDA) has notified the DEA that there are no exemptions or approvals in effect under section 505 of the Federal Food, Drug, and Cosmetic Act for aminorex. A search of the scientific and medical literature revealed no indications of current medical use of aminorex in the United States.

Aminorex is chemically and pharmacologically similar to amphetamine methamphetamine, and cis-4-methylaminorex, all of which are controlled substances with high abuse potential. Like most central nervous system (CNS) stimulants, aminorex produces acute locomotor stimulation in rodents. In drug discrimination studies, aminorex fully substitutes for amphetamine in rats and monkeys and for cocaine in rats. The reinforcing effects of aminorex were evaluated in rhesus monkeys and baboons. Aminorex is self-administered in both experimental paradigms. Collectively, these data indicate that aminorex has an abuse liability and dependence profile similar to other potent controlled CNS stimulants.

The earliest confirmed trafficking of aminorex was in Florida in 1989. Since that time, forensic laboratories have identified aminorex in more than 70 exhibits submitted by law enforcement personnel in Florida, New Jersey, Michigan, Minnesota, Missouri, Pennsylvania, and South Carolina. Clandestine laboratories engaged in the synthesis of aminorex have been discovered in Florida, Pennsylvania, and South Carolina.

Aminorex is orally active but the most common route of administration is via nasal insufflation. It is usually sold as amphetamine or methamphetamine. There has been one death in 1990 associated with aminorex abuse in the United States. Abuse of aminorex produces the same public health risks as those associated with other clandestinely produced stimulants such as methamphetamine with the additional risk factor of pulmonary hypertension.

The DEA Administrator, based on the information gathered and reviewed by his staff and after consideration of the factors in 21 U.S.C. 811(c), believes that sufficient data exists to propose and to support that aminorex be placed into Schedule I of the CSA pursuant to 21 U.S.C. 811(a) The specific findings required pursuant to 21 U.S.C. 811 and 812 for a substance to be placed into Schedule I are as follows:

(1) The drug or other substance has a high potential for abuse.

(2) The drug or other substance has no currently accepted medical use in treatment in the United States.

(3) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Before issuing a final rule in this matter, the DEA Administrator will take into consideration the scientific and medical evaluation and scheduling recommendation of the Secretary of the Department of Health and Human Services in accordance with 21 U.S.C. 811(b) The Administrator will also consider relevant comments from other concerned parties.

Interested persons are invited to submit their comments, objections, or requests for a hearing in writing with regard to this proposal. Requests for a hearing should state with particularity the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted to the Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative. In the event that comments, objections, or requests for a hearing raise one or more issues which the Administrator finds warrants a hearing, the Administrator shall order a public hearing by notice of the Federal Register, summarizing the issues to be heard and setting the time for the hearing.

The Administrator of the DEA hereby certifies that proposed placement of aminorex into Schedule I of the CSA will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act. 5 U.S.C. 601 et seq. This action involves the control of a substance with no currently accepted medical use or manufacture in the United States.

This proposed rulemaking is not a major rule for the purposes of Executive Order 12291 (46 FR 13193) of February 17, 1981. It has been determined that drug scheduling matters are subject to review by the Office of Management and Budget (OMB) pursuant to the provisions of Executive Order 12291. Accordingly, this drug scheduling action is not subject to the provisions of Executive Order 12778 which are contingent on review by OMB.
This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this proposed rulemaking 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(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of the DEA by the Department of Justice regulations (28 CFR 0.100), the Administrator hereby proposes that 21 CFR part 1308 be amended as follows:

PART 1308—[AMENDED]

1 The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871b, unless otherwise noted.

2. Section 1308.11 is amended by adding paragraph (f)(6) to read as follows:

§ 1308.11 Schedule l.

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3 Section 1308.11 is further amended by removing and reserving paragraph (g)(4).


Robert C. Bonner,
Administrator of Drug Enforcement.

[FR Doc. 93–20519 Filed 8–19–93; 8:45 am]

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AG01

Confidentiality of Healthcare Quality Assurance Reviews

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its regulations which govern the confidentiality of documents produced in VA healthcare quality assurance programs. These regulations specify and provide for the limited disclosure of those quality assurance documents which are confidential under the provisions of the Department of Veterans Affairs Healthcare Personnel Act of 1991.

DATES: Comments must be received on or before September 30, 1993. Comments will be available for public inspection until September 30, 1993. It is proposed to make these amendments effective 30 days after the date of publication of the final rule.

ADDRESSES: Interested persons are invited to submit written comments, suggestions, or objections regarding these proposed amendments to: Secretary of Veterans Affairs (271A), 810 Vermont Avenue NW., Washington, DC 20420. All written comments received will be available for public inspection only in the Veterans Service Unit, room 170 at the above address, between the hours of 8 a.m. and 4:30 p.m. Monday through Friday (except holidays), until September 30, 1993.

FOR FURTHER INFORMATION CONTACT: Galen L. Barbour, M.D. Associate CMD for Quality Management (15), 810 Vermont Avenue NW., Washington, DC 20420

SUPPLEMENTARY INFORMATION: This revision of the regulations in 38 CFR part 17 applies to healthcare quality assurance records and documents created after the date on which the revision is published in final form. The previous regulations are still applicable to records and documents created prior to that date and remain protected by 38 U.S.C. 5705 (formerly 38 U.S.C. 3305), Confidentiality of Medical Quality Assurance Records. Records generated for reviews which are initiated prior to the effective date of this revision and are in accordance with the previous regulations are protected by the previous regulations even if the records are completed after the effective date of this revision.

This revision is necessary to update the previous regulations which were published in 1982. Much of the language in those regulations no longer reflects the practice and terminology of quality assurance.

These revised regulations describe the conditions determining the confidentiality of documents produced in quality assurance programs. They do not specify the quality assurance program requirements for VA medical facilities; the rapidly changing environment to which quality assurance programs respond requires that policy guidance on this subject be presented in a more flexible and readily modifiable format. Consequently, the Veterans Health Administration (VHA) will publish a policy document delineating the specific quality assurance requirements for VA medical facilities and the oversight responsibilities of VHA regarding these requirements prior to the final publication of these regulations.

The revised regulations allow confidential information concerning a provider to be seen by that provider for educational and quality improvement purposes. To protect the integrity of the peer review process, the identities of the peer reviewers involved in the creation of the data will not be disclosed to the provider, to the extent practicable. We believe these changes will permit a flow of information conducive to continuous quality improvement by making information on their practice readily available to clinicians.

Confidential information concerning the number of cases treated and procedures performed by individual providers will no longer be protected by 38 U.S.C. 5705 and these regulations. Consequently, 38 U.S.C. 5705 no longer constitutes a bar to releasing this information in a practitioner’s credentialing and privileging folder. Since this information is important to the evaluation of a practitioner’s request for renewal of clinical privileges, making it more readily available should increase the effectiveness of that process.

The classes of systematic healthcare reviews and the specific samples of programs and activities cited in §17.501(a) are included to provide guidance to VA facilities in classifying their review documents to simplify coverage under these regulations. Documents from other systematic healthcare quality assurance reviews which meet the criteria in §17.501 (b) and (c) are also confidential.

It is expected that VA facilities will indicate on all confidential review documents created after the publication of these regulations that the document is confidential under 38 U.S.C. 5705 and these regulations and also will designate the specific program or activity within which the review is included. The program and activity names used should be from the policy documents described in §17.501(b). However, it is not necessary for the facility to have taken these steps for a document which meets the criteria in §17.501 to be confidential and privileged.

These regulations recognize that there are two types of external reviews of care conducted by VA Central Office and the Regions. One type generates documents which are made confidential and privileged by 38 U.S.C. 5705 while the documents resulting from the second type of external review are not protected.