cordingly, such service does not constitute a trade or business.)

[FR Doc.74-29749 Filed 12-19-74;8:45 am]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[21 CFR Parts 1304, 1308]

CONCENTRATE OF POPPY STRAW

Addition to Schedule II and Authorizing Its Importation

A long-time national policy has been established against the importation of finished narcotic drugs; permitting only the importation of such quantities of crude opium deemed to be necessary to provide for the medical, scientific or other legitimate requirements of the United States for any salt, compound, derivative, or preparation of opium poppy. This policy was first established by the Congress in enactment of the Narcotic Drugs Import and Export Act of May 26, 1922, and was affirmed by the Congress by enactment of the Controlled Substances Import and Export Act of October 27, 1970 (Pub. L. 91-513, Title III; 21 U.S.C. 951 et seq.).

The Congress also provided in the Controlled Substances Import Act of 1970, that the Attorney General (now delegated to the Administrator of the Drug Enforcement Administration) may permit the importation of such quantities of narcotic drugs as he finds necessary to provide for the medicinal, scientific, or other legitimate needs of the United States during an emergency in which domestic supplies of such narcotic drugs are found to be inadequate.

During the past four years, the International Narcotic Control Board has been reporting that some countries (including the United States) have been encountering difficulties in obtaining sufficient opium for medical purposes. The matter was discussed fully at the third special session of the United Nations Commission on Narcotic Drugs at Geneva, February 18-March 1, 1974, where there was general agreement that there is a growing demand for opium poppy derivatives which has not been met by the production of crude opium. Also, in a report (B-173123) issued July 23, 1974, the Comptroller General of the United State indicated that the demand for codeine is increasing in the United States, and that a critical situation could develop without additional sources of supply.

Opium production in 1973 was not sufficient to cover the needs of the drug manufacturers, and it was necessary for the manufacturers to use up their inventories beyond an acceptable level in order to meet immediate and estimated future needs for codeine. The International Narcotic Control Board predicted that by 1974, opium resources and opium requirements would be in balance. Unfortunately, India's production in 1974, which was estimated at 1,139 metric tons in November 1973, was actually only 894 metric tons. The resulting deficit and reduction of opium available to United States manufacturers has been largely covered by the equivalent of approximately 238 metric tons of opium authorized to be released from the national strategic materials stockpile. Estimates of opium production in 1975 are not encouraging. India continues to be the only country that produces opium for exportation, and because opium is an agricultural product vulnerable to climatic hazards such as prolonged rains delaying the planting season, very severe winters, and drought during growing seasons, it would not be in the best interest of the United States to continue to rely exclusively on the importation of crude opium for its medical requirements.

Recent reports from the International Narcotic Control Board have been encouraging in regard to the anticipated supply of poppy straw, which will be available from 1975 onwards. The poppy straw process is designed to extract morphine and other opium poppy alkaloids directly from the poppy straw. This process produces a concentrated liquid form or dried gum or a powder containing opium poppy alkaloids, which is described as "concentrate of poppy straw." The poppy straw process will do much to relieve the imbalance of the world's supply and demand for codeine, but only to the extent that there is sufficient industrial capacity to handle it. Several United States pharmaceutical manufacturers have the capacity to manufacture codeine from concentrate of poppy straw, and can help to expand the capacity to utilize increased harvesting of poppy straw.

In order to remedy the shortage of raw materials, the United States Government has taken and will continue to take various steps, which will be spread over a period of time and coordinated to close the gap between the supply and demand for opium poppy derivatives without tilting the balance in the opposite direction. The first step was the release of stockpiled opium. The second measure is to supplement the imbalance with quantities of raw material other than crude opium, and at the same time maintain control equal to the system now applicable to crude opium. The most appropriate equivalent of crude opium is concentrate of poppy straw, that is, the crude extract of poppy straw in either liquid, solid or powder form, which contains the phenanthrine alkaloids of the opium poppy. Accordingly, in pursuance of his authority under section 1002 of the Controlled Substances Import and Export Act (21 U.S.C. 952) and § 1312.13 of the Code of Federal Regulations (21 CFR 1312.13), the Administrator has determined that beginning January 1, 1975, and until further notice, concentrate of poppy straw may be imported on the basis that an emergency exists in which raw materials for the production of opium poppy alkaloids are inadequate.

Concentrate of poppy straw is included in schedule I of the Single Convention on Narcotic Drugs, and is subject to the full regime of control applicable to substances in that schedule. Therefore, under the provisions of section 201(d) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(d)), the Attorney General is authorized to control concentrate of poppy straw in the schedule of the Act deemed most appropriate to carry out the obligations of the United States. The Drug Enforcement Administration has determined that concentrate of poppy straw should be controlled in schedule II of the Act.

The Drug Enforcement Administration desires that concentrate of poppy straw be subjected to the same controls as opium. Accordingly, special reporting requirements similar to § 1304.33 will be imposed on manufacturers who import concentrate of poppy straw.

Therefore, under the authority vested in the Attorney General by sections 201 (d), 301, and 1002 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 28 of the Code of Federal Regulations, the Administrator hereby proposes that Parts 1304 and 1308 of Title 21 of the Code of Federal Regulations be amended as follows

1. A new § 1304.42 is added as follows:

§ 1304.42 Reports from manufacturers importing concentrate of poppy straw.

(a) Every manufacturer importing concentrate of poppy straw shall submit in addition to Form 333, Form DEA 247 (c) accounting for the importation and for all manufacturing operations performed between importation and the production in bulk of finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary, or other recognized medical standards. Subsequent manufacture from such products, including bottling or packaging operations, shall be accounted for in the returns on DEA Form 333 (1304.38) and its supplements. DEA Form 247(c) shall be submitted quarterly to the Regulatory Investigations Section, Drug Enforcement Administration, Department of Justice, Washington, D.C. 20537, on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The report of manufacture from concentrate of poppy straw shall consist of summaries with supporting detail sheets accounting for original manufacture from concentrate of poppy straw, production from morphine for further manufacture, and also accounting for stocks of concentrate of poppy straw, morphine for further manufacture and other crude alkaloids.

(c) The detail sheets (DEA 247(c)) supporting the summary of original manufacture from concentrate poppy straw shall show separately the amount of concentrated poppy straw imported, the concentrated poppy straw used for the extraction of alkaloids, subsequent manufacture from those alkaloids, and the inventory of concentrated poppy straw at the close of the reporting period.

(d) Upon importation of concentrate of poppy straw, samples will be selected and assays made by the importing manufacturer in a manner and according to a method previously approved by DEA. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

(e) Upon withdrawal of concentrate of poppy straw from customs custody, the importing manufacturer shall assign to each container an identification mark or number by which the concentrate of poppy straw will be associated with the lot assay and identified in reports.

(f) Where factory procedure is such that partial withdrawals of concentrate of poppy straw are made from individual containers, there shall be attached to each container a stock record card on which shall be kept a complete record of all withdrawals therefrom.

(g) Concentrate of poppy straw derivatives which are produced for exclusive use in further manufacturing purposes shall be reported produced when they come into existence in that form in which they are to be so used. Alkaloids or derivatives produced exclusively for distribution shall be reported as produced when manufacture has actually been completed and the finished marketable product ready for packaging and distribution. Such products shall be regarded as ready for packaging and distribution as soon as all processing other than mere packaging has been completed. Products manufactured partly for distribution and partly for use in further manufacture will be reported produced as soon as manufacture is complete and they are ready either for use in further manufacture or for packaging for distribution.

(h) Subject to § 1303.24(c) of this chapter, no accumulations of morphine or other narcotic controlled substances in their pure or near-pure states shall be permitted to remain inactively in process for an unreasonable time in light of efficient industrial practices. All such products nearing completion of their respective processes and approaching a condition of purity shall be carefully protected, promptly completed, and immediately transferred to finished stocks, and reported as produced.

(i) In making conversions of concentrate of poppy straw alkaloids and their salts to anhydrous morphine the quantity of the particular alkaloid or salt in avoirdupois ounces shall be multiplied by a conversion factor arrived at by ascertaining the ratio, carried to the fourth decimal place, between the respective molecular weight of such alkaloid or salt and the molecular weight of anhydrous morphine (285.16), such weights being computed to the third decimal place from the chemical formulae of the substances and the atomic weights of elements, as adopted by the International Committee on Chemical Elements and published in the latest edition of the U.S. Pharmacopoeia.

2. Section 1308.12 is amended by adding a new (b) (5) as follows:

§ 1308.12 Schedule II.

* * * * *

(b) * * *

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrine alkaloids of the opium poppy) ..... 9670.

* * * * *

All interested persons are invited to submit their comments and objections, in writing, regarding this proposal. Comments and objections should be submitted in quintriplicate to the Office of Chief Counsel, Drug Enforcement Administration, Department of Justice, Room 1203, 1405 I Street, Washington, D.C. 20537, and must be received on or before January 22, 1974.

Dated: December 17, 1974.

JOHN R. BARTELS, Jr.,
Administrator,
Drug Enforcement Administration.

[FR Doc.74-29845 Filed 12-19-74;10:00 pm]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[14 CFR Part 39]

[Docket No. 74-WE-51-AD]

McDONNELL DOUGLAS MODEL DC-10-10, DC-10-10F, DC-10-30, AND DC-10-30F AIRPLANES

Proposed Airworthiness Directives

The Federal Aviation Administration is considering amending Part 39 of the Federal Aviation Regulations by adding an airworthiness directive applicable to McDonnell Douglas Model DC-10-10, DC-10-10F, DC-10-30, and DC-10-30F airplanes. There have been failures of fan blades on General Electric CF6 engines that could result in a severing of some wing engine nose cowl bolts causing loss of the cowl due to engine unbalance. Since this condition is likely to exist or develop in other airplanes of the same type design, the proposed airworthiness directive would require modifications of the engine nose cowl attachments per McDonnell Douglas DC-10 Service Bulletin 71-53, dated September 25, 1974, or an equivalent modification approved by the Chief, Aircraft Engineering Division, FAA Western Region.

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the docket number and be submitted in duplicate to the Federal Aviation Administration, Western Region, Attention: Regional Counsel, Airworthiness Rules Docket, P.O. Box 92007 World Way Postal Center, Los Angeles, California 90009. All communications received on or before February 5, 1975, will be considered by the Administrator before taking action upon the proposed rule. The proposals contained in this notice may be changed in light of comments received. All comments will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons.

This amendment is proposed under the authority of sections 313(a), 601, and 603 of the Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421, 1423) and of section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

In consideration of the foregoing, it is proposed to amend § 39.13 of Part 39 of the Federal Aviation Regulations by adding the following new airworthiness directive:

McDONNELL DOUGLAS: Applies to Model DC-10-10, DC-10-10F, DC-10-30, and DC-10-30F airplanes certificated in all categories.

Compliance required within the next 4000 flight-hours after the effective date of this A.D., unless already accomplished.

To minimize the possibility of losing wing engine nose cowl due to severed nose cowl attach bolts and engine unbalance loads, modify the wing engine nose cowls per McDonnell Douglas DC-10 Service Bulletin 71-53, "Powerplant—Cowling—Modify Engine Nose Cowl Attachments," dated September 25, 1974, or later FAA-approved revisions, or an equivalent modification approved by the Chief, Aircraft Engineering Division, FAA Western Region.

Issued in Los Angeles, California on December 11, 1974.

ROBERT O. BLANCHARD,
Acting Director,
FAA Western Region.

[FR Doc.74-29633 Filed 12-19-74;8:45 am]

[14 CFR Part 71]

[Airspace Docket No. 74-CE-27]

TRANSITION AREAS

Proposed Alteration

The Federal Aviation Administration is considering amending Part 71 of the Federal Aviation Regulations so as to revoke and redesignate controlled airspace within the State of Kansas except west of Longitude 99°04'00" W., north of V216, V4-108 and V132 east, and in accomplishing this end to amend the Colby, Kansas, Phillipsburg, Kansas, and Hugo, Colorado, transition areas to eliminate reference to airspace within the State of Kansas.

Interested persons may participate in the proposed rule making by submitting such written data, views or arguments as they may desire. Communications should be submitted in triplicate to the Director, Central Region, Attention: Chief, Air Traffic Division, Federal Aviation Administration, Federal Building, 601 East 12th Street, Kansas City, Mo. 64106. All communications received on or before January 20, 1975, will be considered before action is taken on the proposed amendments. No public hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Administration