

2. FLT CONTROL A Switch * * * OFF
—Verify Flight Controls LOW PRESSURE Light illuminates within 2 seconds.
3. FLT CONTROL A Switch * * * ON
—Verify Flight Control LOW PRESSURE Light extinguishes.
4. FLT CONTROL B Switch * * * OFF
—Verify Flight Controls LOW PRESSURE Light illuminates within 2 seconds.
5. FLT CONTROL B Switch * * * ON
—Verify Flight Controls LOW PRESSURE Light extinguishes.

Note: Failure of the Flight Control LOW PRESSURE Light to illuminate within 2 seconds may indicate a failure of the related flight control module.

Autopilot Check

1. Ensure IRUs are in the NAV mode
2. A/P ENGAGE Switch * * * CMD A
—Wait 10 seconds, and verify light remains ON
3. Disengage A autopilot
4. A/P ENGAGE Switch * * * CMD B
—Wait 10 seconds, and verify light remains ON
5. Disengage B autopilot
6. To fail this test, one autopilot will fail to engage and the other will fail to stay engaged.

Note: Failure of the autopilots to engage as described in Step 6. may indicate a failure of a flight control module.

Warning: If either Pre-Flight FCM Checks fails, do not takeoff until the failed module has been replaced."

(f) If required by paragraph (c), (d)(1), or (m) of this AD: Revise the Limitations Section of the FAA-approved AFM to include the following statement (this may be accomplished by inserting this AD into the AFM): "If a flight control module (FCM), having P/N 65-44891-7 with S/N 8726 or greater is installed, the 'Pre-Flight Flight Control Module (FCM) Checks' specified in the Normal Procedures of this AFM must be accomplished before each flight. If either Pre-Flight FCM Checks fails, do not takeoff until the failed module has been replaced."

(g) If required by paragraph (c), (d)(1), or (m) of this AD: Revise the Non-Normal Procedures Section of the FAA-approved AFM to include the following (this may be accomplished by inserting this AD into the AFM):

Flight Control Module (FCM) Failure

Note: If the module fails in flight, neither A nor B autopilot will engage. Other indications include possible increase in flight control forces (similar to manual reversion) and possible yaw damper disengagement.

Failure of a second module in flight could result in serious degradation of airplane controllability, including high control forces.

If a failure is suspected in flight:

- Plan to land at the nearest suitable airport
- Crosswind capability may be reduced
- Do not turn off any flight control switches
- Plan a flaps 15 landing
- Use VREF 15 + 5 or VREF ICE + 5"

Note 2: The Limitations, Non-Normal Procedures, and Normal Procedures specified

by paragraphs (e) through (g) of this AD are required to be implemented only for airplanes on which suspect FCMs have been installed. However, individual pilots may operate other airplanes on which those suspect FCMs have not been installed, and that are not subject to those limitations and procedures. Therefore, to avoid any confusion or misunderstanding, it is important that airlines have communication mechanisms in place to ensure that pilots are aware, for each flight, whether the Limitations, Non-Normal Procedures, and Normal Procedures apply.

Failures Detected During "Flight Control Check"

(h) If any failure is detected during any "Pre-Flight Flight Control Module (FCM) Checks" specified in paragraph (e) of this AD, or during operation of the airplane, before further flight, replace the affected FCM with an FCM identified in paragraph (c)(1), (c)(2), or (c)(3) of this AD.

Reporting Requirement

(i) Submit a report of inspection findings to the Boeing Renton Airline Support Manager, Craig Blankenstein, 2925 South 112th Street, Seattle, Washington 98168; fax (206) 544-9698; at the applicable time specified in paragraph (i)(1) or (i)(2) of this AD. (The report must include the airplane line number and FCM P/N and S/N.) Information collection requirements contained in this AD have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120-0056.

(1) For airplanes on which the inspection required by paragraph (a) of this AD is accomplished after the effective date of this AD: Submit the report within 10 days after performing the inspection required by paragraph (a) of this AD.

(2) For airplanes on which the inspection required by paragraph (a) of this AD has been accomplished before receipt of AD 2002-19-51: Submit the report within 10 days after the effective date of this AD.

Part Installation

(j) For all airplanes: After the effective date of this AD, no person shall install an FCM having P/N 65-44891-7 with a S/N 8726 or greater, on any airplane, unless the compensator has been replaced with a compensator, approved for installation on FCM, P/N 65-44891-7, other than a compensator having P/N 10-60560-3 with S/N 20478A or greater.

(k) After the effective date of this AD, no person shall install a compensator having P/N 10-60560-3 with S/N 20478A or greater, on any FCM.

Alternative Methods of Compliance

(l) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance

Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(m) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished, provided that the airplane is operated per the requirements of paragraphs (e) through (g) of this AD, and that there are no known FCM failures upon dispatch.

Effective Date

(n) This amendment becomes effective on October 15, 2002, to all persons except those persons to whom it was made immediately effective by emergency AD 2002-19-51 R1, issued on September 18, 2002, which contained the requirements of this amendment.

Issued in Renton, Washington, on October 1, 2002.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02-25458 Filed 10-4-02; 8:45 am]

BILLING CODE 4910-13-P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1, 3, 4, 9, 11, 16, 17, 18, 19, 21, 31, 36, 37, 38, 39, 40, 41, 140, 145, 150, 170, 171 and 190

Changes in Divisional Structure and Delegations of Authority

AGENCY: Commodity Futures Trading Commission.

ACTION: Final rules.

SUMMARY: The Commission is amending its rules to reflect the reassignment of responsibilities, including delegations of authority, resulting from its recent reorganization of Commission staff. Effective July 1, 2002, the Commission reassigned the responsibilities of the former Division of Trading and Markets and Division of Economic Analysis to the newly established Division of Clearing and Intermediary Oversight, Division of Market Oversight and Office of the Chief Economist. The reorganized divisions will more effectively implement the provisions of the Commodity Futures Modernization Act of 2000 (CFMA).

EFFECTIVE DATE: October 7, 2002.

FOR FURTHER INFORMATION CONTACT: Paul M. Architzel, Division of Market Oversight, Commodity Futures Trading

Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone 202-418-5260. E-mail: [parchitzel@cftc.gov].

SUPPLEMENTARY INFORMATION: On December 21, 2000, the President signed into law the Commodity Futures Modernization Act of 2000 ("CFMA") which extensively revises the Commodity Exchange Act (Act)¹ In order to more effectively implement its provisions, the Commission has reorganized its operating divisions. Under the reorganized structure, the Division of Trading and Markets and the Division of Economic Analysis (the former divisions) has been reconfigured into two new divisions, the Division of Clearing and Intermediary Oversight and the Division of Market Oversight (the new divisions), and the Office of the Chief Economist.

The Commission is amending several of its rules in Chapter I of Title 17 of the Code of Federal Regulations to reflect this reorganized structure. Accordingly, as indicated in the chart below, the Commission is deleting from its rules references to the former divisions and replacing them with references to the new divisions. As amended, the rules will reflect the new assignments of responsibilities, including delegated authorities, to the two new divisions.

The Commission is also amending rule 140.99, which governs requests for exemptive, no-action and interpretative letters. Before its amendment, rule 140.99 required all requests to be filed with the Division of Trading and Markets, and thereafter routed to the appropriate office or division. The

Commission has determined that it will be more efficient to require the requester to file the request directly with the division with operating responsibility for administering the provision of the Act or of the Commission's regulations from which relief is sought.

Accordingly, the Commission is amending rule 140.99 to require that requests relating to certain specific subject matter areas (as enumerated in the amended rule) be filed with the division with operating responsibility for that subject matter area.

The Commission is deleting rule 140.100 which it adopted on July 9, 2002, 67 FR 45299. That rule provided that all delegations of authority from the Commission to the Directors of the former divisions, and their respective designees, as set forth in Chapter I of Title 17 of the Code of Federal Regulations, were delegated jointly to the respective Directors of the new divisions, and their respective designees. Now that the Commission has amended several of its rules to reflect the new agency structure, rule 140.100 is no longer necessary. Finally, the Commission is removing and reserving rules 1.41a, 1.41c and 1.42, which have been superseded by the CFMA²

Related Matters

Administrative Procedure Act

The Commission has determined that restructuring of responsibilities, including delegations of authority, relates solely to agency organization, procedure and practice. Therefore, the provisions of the Administrative

Procedure Act that generally require notice of proposed rulemaking and that provide other opportunities for public participation are not applicable.³ The Commission further finds that, because the rules have no adverse effect upon a member of the public, there is good cause to make them effective immediately upon publication in the **Federal Register**.

List of Subjects

17 CFR Part 1

Brokers, Commodity futures, Reporting and recordkeeping requirements.

17 CFR Part 140

Authority delegations (Government agencies), Organization and functions (Government agencies).

In consideration of the foregoing, and pursuant to the authority contained in the Act, and in particular section 2(a)(11) of the Act, 7 U.S.C. 2(a)(11), as amended, the Commission hereby amends Parts 1, 3, 4, 9, 11, 16, 17, 18, 19, 21, 31, 36, 37, 38, 39, 40, 41, 140, 145, 150, 170, 171, and 190 of Chapter I of Title 17 of the Code of Federal Regulations as follows:

17 CFR Parts 1, 3, 4, 9, 11, 16, 17, 18, 19, 21, 31, 36, 37, 38, 39, 40, 41, 140, 145, 150, 170, 171 and 190

1. In the table below, for each section indicated in the left column, remove the words indicated in the middle column from wherever they appear in the section, and add the words indicated in the right column:

Section	Remove	Add
1.12(g)(3)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
1.12(h)	Division of Trading Markets	Division of Clearing and Intermediary Oversight.
1.62(b)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
1.62(b)	Attn: Chief Counsel,	Attn:
1.65(d)	Chief Counsel, Division of Trading and Markets	Deputy Director, Compliance and Registration Section, Division of Clearing and Intermediary Oversight.
1.66(b)(5)(ii)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
3.12(g)(2)(i)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
3.12(g)(2)(ii)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
3.22	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
3.33(e)	Division of Trading and Markets, Registration Unit ..	Division of Clearing and Intermediary Oversight.
3.50(c)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
3.50(d)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
3.55(e)(2)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
3.56(e)(2)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
3.63	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
3.70(a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.

¹ The Commodity Exchange Act may be found at 7 U.S.C. 1 *et seq.* (2000), as amended by the Commodity Futures Modernization Act of 2000, Appendix E of Pub. L. 106-554, 114 Stat. 2763 (2000).

² Section 15 of the Commodity Exchange Act, as amended by the CFMA, provides that before promulgating a regulation under this Act or issuing an order, the Commission shall consider the costs and benefits of the action of the Commission. These rules govern internal agency organization,

procedure, and practice, and therefore the Commission finds that none of the considerations enumerated in section 15(a)(2) of the Act, as amended, are applicable to these rules.

³ 5 U.S.C. 553 (1994).

Section	Remove	Add
3.70(a)	Chief Counsel	Deputy Director, Compliance and Registration Section.
Pt. 3 App. A,	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
4.2(a)	Managed Funds Branch, Division of Trading and Markets.	Division of Clearing and Intermediary Oversight.
9.2(h)	Division of Trading and Markets	Division of Market Oversight and/or the Division of Clearing and Intermediary Oversight.
9.11(c)	Contract Markets Section, Division of Trading and Markets.	Division of Market Oversight.
9.12(b)	Division of Trading and Markets	Division of Market Oversight.
9.26, first sentence	Within twenty days after the receipt by the Division of Trading and Markets of the answering brief, the Division of Trading and Markets * * *..	Within twenty days after receipt of the answering brief, the Division of Market Oversight and/or the Division of Clearing and Intermediary Oversight * * *
9.26, last sentence	No employee of the Division of Trading and Markets	No employee of the Division(s) filing the notice.
9.31(a)	Division of Trading and Markets	Division of Market Oversight or the Division of Clearing and Intermediary Oversight.
11.2(a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
11.2(a)	Division of Economic Analysis	Division of Market Oversight.
16.07	Division of Economic Analysis	Division of Market Oversight.
17.03	Division of Economic Analysis	Division of Market Oversight.
18.03	Division of Economic Analysis	Division of Market Oversight.
19.00(a)(3)	Division of Economic Analysis	Division of Market Oversight.
21.02a(c)	Division of Economic Analysis	Division of Market Oversight.
31.6(f)(1)	Division of Economic Analysis	Division of Market Oversight.
31.6(f)(2)	Division of Economic Analysis	Division of Market Oversight.
31.13(n)(1)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
31.14(a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
31.14(a)	Division of Economic Analysis	Division of Market Oversight.
36.3(b)(2)(ii)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
36.3(b)(2)(ii)	Economic Analysis	The Division of Market Oversight.
37.5(f)(1)	Division of Trading and Markets and separately to the Director of Economic Analysis or such other employee or employees as the Directors.	Division of Market Oversight or such other employee or employees as the Director.
37.5(f)(2)	Directors	Director.
37.8(d)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
37.8(d)	Division of Economic Analysis	Division of Market Oversight.
38.3(e)(1)	Division of Trading and Markets and separately to the Director of Economic Analysis or such other employee or employees as the Directors.	Division of Market Oversight or such other employee or employees as the Director.
38.3(e)(2)	Directors	Director.
38 App B, Core Principle 11, (a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
39.3(e)(1)–(2)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
40.7(a)(1)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
40.7(a)(1)	Economic Analysis	The Division of Market Oversight.
40.7(a)(2)	Director of the Division of Trading and Markets, or the delegates of the Director.	Directors of Division of Market Oversight and Division of Clearing and Intermediary Oversight or the delegates of the Directors.
40.7(b), introductory text	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
40.7(b), introductory text	Economic Analysis	The Division of Market Oversight.
41.33(g)	Division of Trading and Markets and the Director of the Division of Economic Analysis, jointly.	Division of Market Oversight.
41.33(g)(1)	Division of Trading and Markets or the Director of the Division of Economic Analysis.	Division of Market Oversight.
41.33(g)(2)	Division of Trading and Markets and the Director of the Division of Economic Analysis.	Division of Market Oversight.
41.3(d)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.72(a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.72(a)	Division of Economic Analysis	Division of Market Oversight.
140.73(a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.73(a)	Division of Economic Analysis	Division of Market Oversight.
140.73(b)	Division of Economic Analysis	Division of Market Oversight.
140.74(a)	Division of Economic Analysis	Division of Market Oversight.
140.74(b)	Division of Economic Analysis	Division of Market Oversight.
140.74(c)	Division of Economic Analysis	Division of Market Oversight.
140.75	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.76(a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.76(b)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.77(a)	Director of the Division of Economic Analysis and the Division of Trading and Markets or their.	Director of the Division of Market Oversight or the Director's.
140.77(b)	Directors of the Division of Economic Analysis and the Division of Trading and Markets may submit any matter which has been delegated to them.	Director of the Division of Market Oversight may submit any matter which has been delegated to the director.

Section	Remove	Add
140.77(c)	Directors of the Division of Economic Analysis and the Division of Trading and Markets.	Director of the Division of Market Oversight.
140.91(a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.91(b)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.92(a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.92(b)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.92(c)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.93(a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.93(b)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.93(c)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.95(a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.95(b)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.94(c)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.96(a)	Division of Economic Analysis	Division of Market Oversight.
140.96(b)	Division of Economic Analysis	Division of Market Oversight.
140.96(b)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.96(c)	Division of Economic Analysis	Division of Market Oversight.
140.96(c)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.96(d)	Division of Economic Analysis	Division of Market Oversight.
140.96(d)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.97(a)	Division of Economic Analysis	Division of Market Oversight.
140.97(b)	Division of Economic Analysis	Division of Market Oversight.
140.97(c)	Division of Economic Analysis	Division of Market Oversight.
140.99(a)(5)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
140.99(a)(5)	Division of Economic Analysis	Division of Market Oversight.
140.735-2a footnote 7	Division of Economic Analysis	Division of Market Oversight.
145.6(a)	Division of Economic Analysis, Commodity Futures Trading Commission, One World Trade Center, Suite 3747, New York, New York 10048, Telephone: (212) 466-2061.	Commodity Futures Trading Commission, 140 Broadway, New York, New York 10005 Telephone: (646) 746-9700.
145.6(a)	Division of Trading and Markets, Commodity Futures Trading Commission, 300 South Riverside Plaza, Suite 1600 North, Chicago, Illinois 60606, Telephone: (312) 353-5990.	Commodity Futures Trading Commission, 525 West Monroe Street, Suite 1100, Chicago, Illinois 60661, Telephone: (312) 596-0700.
145.6(a)	Division of Trading and Markets, Commodity Futures Trading Commission, 510 Grain Exchange Building, Minneapolis, Minnesota 55415, Telephone (612) 370-3255.	Commodity Futures Trading Commission, 510 Grain Exchange Building, Minneapolis, Minnesota 55415, Telephone: (612) 370-3255.
145.6(a)	Division of Trading and Markets, Commodity Futures Trading Commission, 4900 Main Street, Suite 721, Kansas City, Missouri 64112, Telephone: (816) 931-7600.	Commodity Futures Trading Commission, 4900 Main Street, Suite 721, Kansas City, Missouri 64112, Telephone: (816) 931-7600.
Pt. 145, App A, (e)	Division of Economic Analysis	Division of Market Oversight.
Pt. 145, App A, (g)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
150.3(b)	Division of Economic Analysis	Division of Market Oversight.
150.4(e)	Division of Economic Analysis	Division of Market Oversight.
170.12	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
171.28	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
171.28	Division of Economic Analysis	Division of Market Oversight.
171.31(a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
171.31(a)	Division of Economic Analysis	Division of Market Oversight.
190.10(a)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
190.10(b)(4)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
190.10(d) heading & (d)(1)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
190.10(d)(2)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.
190.10(d)(3)	Division of Trading and Markets	Division of Clearing and Intermediary Oversight.

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

2. The authority citation for Part 1 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 2a, 4, 4a, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6h, 6i, 6j, 6k, 6l, 6m, 6n, 6o, 6p, 7, 7a, 7b, 8, 9, 12, 12a, 12c, 13a, 13a-1, 16, 16a, 19, 21, 23, and 24.

3. Sections 1.4a, 1.41c, and 1.42 are removed and reserved.

PART 140—ORGANIZATION, FUNCTIONS, AND PROCEDURES OF THE COMMISSION

4. The authority citation for Part 140 continues to read as follows:

Authority: 7 U.S.C. 2 and 12a.

5. Section 140.99 is amended by revising paragraph (d)(2) to read as follows:

§ 140.99 Request for exemptive, no-action and interpretative letters.

* * * * *

(d) Filing requirements. * * *

(1) * * *

(2) A request for a Letter relating to the provisions of the Act or the Commission's rules, regulations or orders governing designated contract markets, registered derivatives transaction execution facilities, exempt commercial markets, exempt boards of trade, the nature of particular

transactions and whether they are exempt or excluded from being required to be traded on one of the foregoing entities, foreign trading terminals, hedging exemptions, and the reporting of market positions shall be filed with the Director, Division of Market Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. A request for a Letter relating to all other provisions of the Act or Commission rules shall be filed with the Director, Division of Clearing and Intermediary Oversight Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. The request must be submitted electronically using the e-mail address *dmoletters@cftc.gov* (for request filed with the Division of Market Oversight), or *dcioletters@cftc.gov* (for requests filed with the Division of Clearing and Intermediary Oversight), as appropriate, and a properly signed paper copy of the request must be provided to the Division of Market Oversight or the Division of Clearing and Intermediary Oversight, as appropriate, within ten days for purposes of verification of the electronic submission.

* * * * *

§ 140.100 [Removed]

6. Section 140.100 is removed.

Issued in Washington, DC, this 26th day of September, 2002, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 02-25049 Filed 10-4-02; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR part 1308

[DEA-225F]

Schedules of Controlled Substances: Rescheduling of Buprenorphine From Schedule V to Schedule III

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to reschedule buprenorphine from a Schedule V narcotic to a Schedule III narcotic under the Controlled Substances Act (CSA). This action is based on a rescheduling recommendation by the Department of Health and Human Services (DHHS) and a DEA review indicating that buprenorphine meets the criteria of a Schedule III narcotic. The DEA published a proposed rule to reschedule buprenorphine on March 21, 2002 (67 FR 13114). The comment period was extended for an additional 30 days until May 22, 2002 (67 FR 20072). The DEA received ten comments but no requests for hearings.

This final action will impose the regulatory controls and criminal sanctions of a Schedule III narcotic on those persons who handle buprenorphine or products containing buprenorphine.

DATES: Effective Date: October 7, 2002. Compliance to some regulatory requirements may be delayed as noted in the Regulatory Requirements section of this document.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, (202) 307-7183.

SUPPLEMENTARY INFORMATION:

Background

Buprenorphine is a semisynthetic opioid. As a derivative of thebaine, buprenorphine was controlled in Schedule II of the CSA in 1970 and remained in Schedule II during its research and development for marketing. In 1981, buprenorphine hydrochloride (Buprenex®) was approved for marketing in the United States as an injectable formulation (0.3 mg/ml) for the treatment of moderate to severe pain. The DEA proposed placement of buprenorphine in Schedule V of the CSA after receiving a medical and scientific evaluation and a Schedule V recommendation from the DHHS. However, buprenorphine was not placed in Schedule V of the CSA until April 1, 1985 (50 FR 8104, February 28, 1985) due to a hearing requested by the manufacturer of buprenorphine, Reckitt & Coleman (now Reckitt Benckiser). Since 1985, Buprenex® has remained in Schedule V. As an injectable analgesic, this product has had limited use outside hospital and clinic settings and is the only buprenorphine product presently marketed in the United States.

In December 2001, the DHHS forwarded a recommendation to reschedule buprenorphine to Schedule III of the CSA. This recommendation was based on a reevaluation of buprenorphine's abuse potential and dependence profile in light of numerous scientific studies and years of human experience with this drug. The DHHS compared buprenorphine with other drugs that share similar pharmacological properties and/or medical utility and considered both foreign and domestic data especially in regard to formulations of buprenorphine that are likely to become available for use in the United States. Two New Drug Applications (NDA) have been submitted to the Food and Drug Administration (FDA) for high dose sublingual (under the tongue) tablets. These potential addiction treatment products include: (1) Subutex®, a mono or single entity buprenorphine product (2 and 8 mg tablets), and (2) Suboxone®, a combination product in a 4:1 ratio of buprenorphine to naloxone (2: 0.5 and 8: 2 mg tablets). The Subutex® and Suboxone® NDAs remain pending at the FDA but approvable letters have been issued for both products and they are likely to receive final marketing approval in 2002. Low dose sublingual tablets (0.1, 0.2 and 0.4 mg) have been available in numerous countries throughout the world and, in recent years, high dose sublingual tablets (2 and 8 mg) have been introduced in many countries for the treatment of opioid dependence.

After consideration of the DHHS scientific and medical evaluation and Schedule III recommendation, the DEA completed an independent eight factor analysis that included the following factors in accordance with 21 U.S.C. 811(c):

- (1) Its actual or relative potential for abuse;
- (2) Scientific evidence of its pharmacological effects;
- (3) The state of current scientific knowledge regarding the drug;
- (4) Its history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) What, if any, risk there is to the public health;
- (7) Its psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

On March 21, 2002, the DEA published a proposed rule to place buprenorphine in Schedule III of the CSA (67 FR 13114). This notice will