administrative law judge mails a notice of his or her hearing decision.

8. Amend §416.1442 by revising paragraphs (d), (e) introductory text, (e)(1), and (f)(3) to read as follows:

§416.1442 Prehearing proceedings and decisions by attorney advisors.

(d) Notice of a decision by an attorney advisor. If an attorney advisor issues a fully favorable decision under this section, we will mail a written notice of the decision to all parties at their last known addresses. We will state the basis for the decision and advise all parties that they may request that an administrative law judge reinstate the request for a hearing if they disagree with the decision for any reason. Any party who wants to make this request must do so in writing and send it to us within 60 days of the date he or she receives notice of the decision. The administrative law judge will extend the time limit if the requestor shows good cause for missing the deadline. The administrative law judge will use the standards in §416.1411 to determine whether there is good cause. If the request is timely, an administrative law judge will reinstate the request for a hearing and offer all parties an opportunity for a hearing.

(e) Effect of an attorney advisor’s decision. An attorney advisor’s decision under this section is binding unless—

(1) You or another party to the hearing submits a timely request that an administrative law judge reinstate the request for a hearing under paragraph (d) of this section;

(2) The notice of appeal is mailed within 60 days after the date of the decision under §416.1469.

9. Amend §416.1448 by revising the second sentence of paragraph (a), and paragraph (b)(1)(ii), to read as follows:

§416.1448 Deciding a case without an oral hearing before an administrative law judge.

(a) Decision fully favorable. The notice of the decision will state that you have the right to an oral hearing and to examine the evidence on which the administrative law judge based the decision.

(b)(1) * * *

(ii) You live outside the United States, you do not inform us that you wish to appear, and there are no other parties who wish to appear.

* * * * * * * *

10. Revise §416.1460 to read as follows:

§416.1460 Vacating a dismissal of a request for a hearing before an administrative law judge.

(a) Except as provided in paragraph (b) of this section, an administrative law judge or the Appeals Council may vacate a dismissal of a request for a hearing if you request that we vacate the dismissal. If you or another party wish to make this request, you must do so within 60 days of the date you receive notice of the dismissal, and you must state why our dismissal of your request for a hearing was erroneous. The administrative law judge or Appeals Council will inform you in writing of the action taken on your request. The Appeals Council may also vacate a dismissal of a request for a hearing on its own motion. If the Appeals Council decides to vacate a dismissal on its own motion, it will do so within 60 days of the date we mail the notice of dismissal and will inform you in writing that it vacated the dismissal.

(b) If you wish to proceed with a hearing after you received a fully favorable revised determination under the prehearing case review process in §416.1441, you must follow the procedures in §416.1441(d) to request that an administrative law judge vacate his or her order dismissing your request for a hearing.

[FR Doc. 2011–27236 Filed 10–20–11; 8:45 am]  
BILLING CODE 4191–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–357]

Schedules of Controlled Substances: Temporary Placement of Three Synthetic Cathinones into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final Order.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) is issuing this final order to temporarily schedule three synthetic cathinones under the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of 21 U.S.C. 811(h). The substances are 4-methyl-N-methylcathinone (mephedrone), 3,4-methylenedioxymethylcathinone (methylone), and 3,4-methylenedioxymethylpentylone (MDPV).

This action is based on a finding by the Administrator that the placement of these synthetic cathinones and their salts, isomers, and salts of isomers into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. As a result of this order, the full effect of the CSA and its implementing regulations including criminal, civil and administrative penalties, sanctions and regulatory controls of Schedule I substances will be imposed on the manufacture, distribution, possession, importation, and exportation of these synthetic cathinones.

DATES: Effective Date: This Final Order is effective on October 21, 2011.

FOR FURTHER INFORMATION CONTACT: Imelda L. Paredes, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone (202) 307–7165.

SUPPLEMENTARY INFORMATION:

Background

The Comprehensive Crime Control Act of 1984 (Pub. L. 98–473), which was signed into law on October 12, 1984, amended section 201 of the CSA (21 U.S.C. 811) to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA for one year without regard to the requirements of 21 U.S.C. 811(b) if he finds that such action is necessary to avoid imminent hazard to the public safety. 21 U.S.C. 811(h); 21 CFR 1308.49. If proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling up to an additional six months. 21 U.S.C. 811(h)(2). Where the necessary findings are made, a substance may be temporarily scheduled in Schedule I if it is not listed in any other schedule under section 202 of the CSA (21 U.S.C. 812) or if there is no exemption or approval in effect under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for the substance. 21 U.S.C. 811(h)(1). The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of DEA. 28 CFR 0.100.

Section 201(b)(4) of the CSA (21 U.S.C. 811(h)(4)) requires the Administrator to notify the Secretary of Health and Human Services of her intention to temporarily place a substance into Schedule I of the CSA.

1 Because the Secretary of Health and Human Services has delegated to the Assistant Secretary for...
The Administrator transmitted notice of her intent to place mephedrone, methylone and MDPV in Schedule I on a temporary basis to the Assistant Secretary in a letter dated June 15, 2011. The Assistant Secretary responded to this notice by letter dated July 25, 2011, and advised that based on review by the Food and Drug Administration (FDA) there are currently no investigational new drug applications (INDs) or approved new drug applications (NDAs) for MDPV, mephedrone, or methylone. The Assistant Secretary also stated that the Department of Health and Human Services has no objection to the temporary placement of MDPV, mephedrone, and methylone into Schedule I of the CSA. DEA has taken into consideration the Assistant Secretary’s comments. As MDPV, mephedrone, and methylone are not currently listed in any schedule under the CSA, as no exemptions or approvals are in effect for MDPV, mephedrone, and methylone under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and as this temporary scheduling is necessary to avoid an imminent hazard to the public safety, DEA believes that the conditions of 21 U.S.C. 811(h)(1) have been satisfied. A notice of intent to temporarily place mephedrone, methylone, and MDPV into Schedule I of the CSA was published in the Federal Register on September 8, 2011 (76 FR 55616). The data in support of the notice of intent and additional data continue to support the necessary findings to place mephedrone, methylone, and MDPV temporarily into Schedule I of the CSA as necessary to avoid an imminent hazard to the public safety. In making this finding, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA (21 U.S.C. 811(c)). These factors are as follows: The substance’s history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(c)(4)–(6).

Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, as well as the potential for abuse in the United States. As a result of this abuse, synthetic cathinones are banned in at least 37 states in the United States and several countries, and all five branches of the U.S. military prohibit military personnel from possessing or using synthetic cathinones. Second, law enforcement has seized synthetic cathinones and, based on self-reports to law enforcement and health care professionals, synthetic cathinones are abused for their psychoactive properties. Third, federal, state and local public health departments and poison control centers have issued reports describing public health consequences such as emergency department visits and deaths from the use of these synthetic cathinones. Based on scientific data currently available, these three substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety.

**Factor 4: History and Current Pattern of Abuse**

Synthetic cathinones are designer drugs of the phenethylamine class which are structurally and pharmacologically similar to amphetamine. MDMA, cathinone and other related substances. The addition of a beta-keto (β-keto) substituent to the phenethylamine core structure produces a group of substances that now have cathinone as the core structure. Synthetic cathinones, like amphetamine, cathinone, methcathinone, and methamphetamine, are central nervous system (CNS) stimulants.

The synthetic cathinones mephedrone, methylone, and MDPV have recently emerged on the United States’ illicit drug market and are being perceived as being ‘legal’ alternatives to cocaine, methamphetamine, and MDMA. Although synthetic cathinones are new to the United States’ illicit drug market, they have been popular drugs of abuse in Europe since 2007. MDPV is a derivative of pyrovalerone, which is a psychoactive drug that was used to treat chronic lethargy and fatigue. Research in animal models and anti-parkinson agents resulted in the development and patenting of methylone. Methylone, however, has not been approved for these purposes. There are no currently accepted medical uses in treatment in the United States for mephedrone, methylone, or MDPV.

Mephedrone, methylone, and MDPV are falsely marketed as “research chemicals,” “plant food,” or “bath salts.” They are sold at smoke shops, head shops, convenience stores, adult book stores, and gas stations. They can also be purchased on the Internet and mailed using the U.S. Postal Service or international mail services. The packages of products containing these synthetic cathinones usually have the warning “not for human consumption,” most likely in an effort to circumvent statutory restrictions for these substances. Despite disclaimers that the products are not intended for human consumption, retailers promote that routine urinalysis drug tests will not typically detect the presence of these synthetic cathinones. However, analytical methods for the detection of mephedrone, methylone, MDPV, and synthetic cathinones have recently been developed for these substances.

Evidence indicates that mephedrone, methylone, and MDPV are being abused for their psychoactive properties. Drug surveys found that these and other synthetic cathinones are being used as recreational drugs and are used as alternatives to illicit stimulants like MDMA and cocaine. Accordingly, mephedrone, methylone, and MDPV have been identified in human urine samples that were obtained for routine drug screenings, they have been detected in samples from drivers suspected of driving under the influence, and they have been detected by drug courts during mandatory periodic drug screens. They have also been identified in biological specimens from individuals (some exhibiting symptoms of “extreme agitation” or “excited delirium”) who have been arrested for possession of a controlled substance, child endangerment, or homicide. They have been detected in samples from decedents whose causes of death were reported as drug-induced toxicity, multiple drug toxicity, or other causes (e.g., blunt force trauma from a vehicular collision or suicide).

Based on studies in the scientific literature, the marketing of products that contain mephedrone, methylone, and MDPV is geared towards teens and young adults. Accordingly, reports indicate that the main users of synthetic cathinones are young male adults. These substances are also used by mid-to-late adolescents and older adults. Many of these abusers of synthetic cathinones have a previous history of drug abuse.
According to drug surveys, the reported average amount of synthetic cathinones used per dose ranged from approximately 25 to 250 milligrams and the average amount used per session (i.e., repeated administration and binging) ranged from approximately 25 milligrams to 5 grams depending on the substance consumed, duration of intake, and route of administration. The most common routes of administration of these substances are nasal insufflation by snorting the powder and oral ingestion by swallowing capsules or tablets. Other reported methods of administration include injection, rectal administration, and “bombing” (wrapping a dose of powder in a paper wrap and swallowing). Synthetic cathinones have also been reported to be used in binges. Reasons cited for binging include to prolong the duration of effects, to satisfy a “craving,” or to satisfy a strong urge to re-dose.

According to information found in drug surveys, clinical case reports, and law enforcement reports, users have reported using products containing mephedrone, methylone, and MDPV with other synthetic cathinones (e.g., butylone, fluoromethcathinone, 4–MEC, etc.), pharmaceutical agents (e.g., lidocaine, caffeine, benzocaine, etc.), or other recreational substances (e.g., amphetamine, MDMA, cocaine, gamma-butyrolactone (GBL), kratom, N,N-benzylpiperazine (BZP), and 1-(3-trifluoromethylphenyl)-piperazine (TFMPP)). Chemical analyses of seized and purchased synthetic cathinone products indicate that some products contain multiple substances. Furthermore, investigative toxicology reports of drug screens in which more than one substance was detected indicate that users have ingested products composed of drug combinations (e.g., a tablet composed of MDPV and BZP) or multiple drug products (e.g., a MDPV powder product and a MDMA tablet).

**Factor 5: Scope, Duration and Significance of Abuse**

The popularity of synthetic cathinones as recreational drugs has increased since they first appeared on the United States’ illicit drug market. According to forensic laboratory reports, the first appearance of these synthetic cathinones in the United States occurred in 2009. In 2009, NFLIS registered 15 exhibits from 8 states containing these three synthetic cathinones. In 2010, there were 574 reports from 29 states related to these substances registered in NFLIS, and in 2011 (January to August) there were 995.3

Based on reports to DEA from law enforcement and public health officials, synthetic cathinones are becoming increasingly prevalent and abused throughout the United States. At one United States point of entry, the U.S. Customs and Border Protection (CBP) has encountered at least 127 shipments containing primarily mephedrone, methylone, and MDPV, as well as other synthetic cathinones like 4–MEC, butylone, fluoromethcathinone, and dimethylcathinone. Most of these shipments originated in China or India and were being shipped to destinations throughout the United States such as Arizona, Alabama, Hawaii, Kansas, Louisiana, Oklahoma, Oregon, Pennsylvania, Missouri, Virginia, Washington, and West Virginia. The American Association of Poison Control Centers (AAPCC), a non-profit, national organization that represents the poison control centers of the United States, reported that in 2010, poison control centers took 303 calls about synthetic cathinones. However, in just the first eight months of 2011, poison control centers have already received 4,720 calls relating to these products. These calls were received in poison control centers representing at least 47 states and the District of Columbia. Individual state poison control centers have also reported an increase in the number of calls regarding “bath salts” from 2009 to 2011.

Concerns over the abuse of these and other synthetic cathinones have prompted many states to control these substances. As of September 15, 2011, at least 37 states have emergency legislation or enacted legislation placing regulatory controls on some or many of the synthetic cathinones. These states include Alabama, Arkansas, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Michigan, Minnesota, Mississippi, Missouri, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Texas, Tennessee, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. Several countries including all members of the European Union have also placed controls on the possession and/or sale of one or more of these substances. Moreover, the use of synthetic cathinones by members of the U.S. Armed Forces is prohibited.

**Factor 6: What, if Any, Risk There Is to the Public Health**

The risks to the public health associated with the abuse of mephedrone, methylone, and MDPV relate to acute and long term public health and safety problems. These synthetic cathinones have become a serious drug abuse threat as there have been reports of emergency room admissions and deaths associated with the abuse of these substances.

Clinical case reports indicate that these synthetic cathinones produce a number of stimulant-like adverse effects such as palpitation, seizure, vomiting, sweating, headache, discoloration of the skin, hypertension, and hyper-reflexia. Adverse effects associated with consumption of these drugs as reported by abusers include nose-bleeds, bruxism (teeth grinding), paranoia, hot flashes, dilated pupils, blurred vision, dry mouth/thirst, palpitations, muscular tension in the jaw and limbs, headache, agitation, anxiety, tremor, and fever or sweating. Consequently, numerous individuals have presented at emergency departments in response to exposure incidents and several cases of acute toxicity have been reported due to the ingestion of mephedrone, methylone, or MDPV. In addition, case reports have shown that the abuse of synthetic cathinones can lead to psychological dependence like that reported for other stimulant drugs.

According to clinical case reports, investigative toxicological reports, and autopsy reports, mephedrone, methylone, and MDPV have been implicated in drug induced overdose deaths. In at least three reported deaths, one of these synthetic cathinones was ruled as the cause of death. Other deaths involved individuals under the influence of these synthetic cathinones who acted violently and unpredictably in causing harm to themselves or others. There have also been reports in the scientific literature of deaths caused by individuals who were driving under the influence of these synthetic cathinones.

A number of synthetic cathinones and their products, as identified by CBP and reported in the scientific literature, appear to originate from foreign sources. The manufacturers and retailers who make and sell these products do not fully disclose the product ingredients including the active ingredients or the health risks and potential hazards associated with these products. This poses significant risk to abusers who may not know what they are purchasing or the risk associated with the use of these products.

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3 Analyzed on September 15, 2011.
Based on the above data, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of mephedrone, methylone, and MDPV pose an imminent hazard to the public safety. DEA is not aware of any recognized therapeutic uses of these synthetic cathinones in the United States.

DEA has considered the three criteria for placing a substance into Schedule I of the CSA (21 U.S.C. 812), and finds that the data available and reviewed for mephedrone, methylone, and MDPV indicate that these synthetic cathinones each have a high potential for abuse, no currently accepted medical use in treatment in the United States, and lack accepted safety for use under medical supervision.

In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100, the Administrator has considered the available data and the three factors required to support a determination to temporarily schedule three synthetic cathinones (4-methyl-N-methylcathinone, 3,4-methylenedioxy-N-methylcathinone, and 3,4-methylenedioxyprovalerone) in Schedule I of the CSA and finds that placement of these synthetic cathinones and their salts, isomers, and salts of isomers into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

Regulatory Requirements

With the issuance of this final order, mephedrone, methylone, and MDPV become subject to the regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, possession, importation and exportation of a Schedule I controlled substance under the CSA.

1. Registration. Any person who manufactures, distributes, dispenses, imports, exports, or possesses mephedrone, methylone, or MDPV or who engages in research or conducts instructional activities with respect to mephedrone, methylone, or MDPV, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with 21 U.S.C. 823 and 958. Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration and may not continue their activities until DEA has approved that application. Retail sales of Schedule I controlled substances to the general public are not allowed under the Controlled Substances Act.

2. Security. Mephedrone, methylone, and MDPV are subject to Schedule I security requirements. Accordingly, appropriately registered DEA registrants must manufacture, distribute and store these substances in accordance with 1301.71; 1301.72(a), (c), and (d); 1301.73; 1301.74; 1301.75(a) and (c); and 1301.76 of Title 21 of the Code of Federal Regulations as of October 21, 2011.

3. Labeling and packaging. All labeling and packaging requirements for controlled substances set forth in Part 1302 of Title 21 of the Code of Federal Regulations shall apply to commercial containers of mephedrone, methylone, and MDPV. Current DEA registrants shall have thirty (30) calendar days from the effective date of this Final Order to be in compliance with all labeling and packaging requirements.

4. Quotas. Quotas for mephedrone, methylone, and MDPV will be established based on registrations granted and quota applications received pursuant to Part 1303 of Title 21 of the Code of Federal Regulations.

5. Inventory. Every DEA registrant who possesses any quantity of mephedrone, methylone, or MDPV is required to keep inventory of all stocks of these substances on hand pursuant to 1304.03, 1304.04, and 1304.11 of Title 21 of the Code of Federal Regulations. Every current DEA registrant who desires registration in Schedule I for mephedrone, methylone, or MDPV shall conduct an inventory of all stocks of these substances. Current DEA registrants shall have thirty (30) calendar days from the effective date of this Final Order to be in compliance with all inventory requirements.

6. Records. All registrants who handle mephedrone, methylone, or MDPV are required to keep records pursuant to 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations. Current DEA registrants shall have thirty (30) calendar days from the effective date of this Final Order to be in compliance with all recordkeeping requirements.

7. Reports. All registrants are required to submit reports in accordance with 1304.33 of Title 21 of the Code of Federal Regulations. Registrants who manufacture or distribute mephedrone, methylone, or MDPV are required to comply with these reporting requirements and shall do so as of October 21, 2011.

8. Order Forms. All registrants involved in the distribution of mephedrone, methylone, or MDPV must comply with order form requirements of Part 1305 of Title 21 of the Code of Federal Regulations as of October 21, 2011.

9. Importation and Exportation. All importation and exportation of mephedrone, methylone, or MDPV must be conducted by appropriately registered DEA registrants in compliance with Part 1312 of Title 21 of the Code of Federal Regulations on or after October 21, 2011.

10. Criminal Liability. The manufacture, distribution, dispensation, or possession with the intent to conduct these activities: Possession, importation, or exportation of mephedrone, methylone, or MDPV not authorized by, or in violation of the CSA or the Controlled Substances Import and Export Act occurring as of October 21, 2011 is unlawful.

Pursuant to the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act) (5 U.S.C. 801–808), DEA has submitted a copy of this Final Order to both Houses of Congress and to the Comptroller General.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

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 the DEA by Department of Justice regulations (28 CFR 0.100), the Administrator hereby orders that 21 CFR Part 1308 be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for Part 1308 continues to read as follows:

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

2. Section 1308.11 is amended by adding new paragraphs (g)(6), (7) and (8) to read as follows:

§ 1308.11 Schedule I.

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Federal Register / Vol. 76, No. 204 / Friday, October 21, 2011 / Rules and Regulations
This rule is effective November 21, 2011.

ADDITIONS: Comments and related materials received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2011–0268 and are available online by going to http://www.regulations.gov, inserting USCG–2011–0268 in the “Keyword” box, and then clicking “Search.” This material is also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. John W. McDonald, Project Officer, First Coast Guard District Bridge Branch, 617–223–8364, john.w.mcdonald@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

REGULATORY INFORMATION

On June 24, 2011, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations Passaic River in the Federal Register (76 FR 37039). We received no comments on the proposed rule. No public meeting was requested, and none was held.

Basis and Purpose

The Amtrak Dock Bridge, mile 5.0, across the Passaic River at Harrison, New Jersey, has a vertical clearance in the closed position of 24 feet at mean high water and 29 feet at mean low water. The drawbridge operation regulations are listed at 33 CFR 117.739(e).

The existing drawbridge operation regulations require the draw to open on signal; except that, from 7:20 a.m. to 9:20 a.m. and 4:30 p.m. to 6:50 p.m., Monday through Friday, except Federal holidays, the draw need not be opened. At all other times, an opening may be delayed no more than ten minutes, unless the draw tender and the vessel operator, communicating by radio-telephone, agree to a longer delay.

The Coast Guard received a request from the National Railroad Passenger Corporation (Amtrak), the owner of the bridge, for relief from crewing the bridge at all times, because the bridge has received only eight requests to open during the past three years.

Amtrak requested that a twenty-four hour advance notice be required for all bridge openings, except during the existing morning and afternoon closed periods.

As a result of the fact that the bridge has received only eight requests to open during the past three years, the Coast Guard believes it is reasonable for the bridge owner to require a twenty-four hour advance notice for bridge openings and that doing so would continue to meet the reasonable needs of navigation.

Discussion of Comments and Changes

The Coast Guard received no comments in response to the notice of proposed rulemaking. As a result, no changes have been made to this final rule.

REGULATORY ANALYSES

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.