

thereby enabling the facility to treat its waste as non-hazardous.

IV. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act, 5 U.S.C. §§ 602-612, whenever an Agency is required to publish a general notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis which describes the impact of the rule on small entities (*i.e.*, small businesses, small organizations, and small governmental jurisdictions). The Administrator may certify, however, that the rule will not have a significant economic impact on a substantial number of small entities.

This amendment will not have an adverse economic impact on small entities since its effect will be to reduce the overall costs of EPA's hazardous waste regulations. Accordingly, I hereby certify that this proposed regulation will not have a significant economic impact on a substantial number of small entities. This regulation, therefore, does not require a regulatory flexibility analysis.

V. List of Subjects in 40 CFR Part 261

Hazardous waste, Recycling.

Dated: July 18, 1985.

Jack W. McGraw,

Acting Assistant Administrator.

For the reasons set out in the preamble, 40 CFR Part 261 is to be amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for Part 261 continues to read as follows:

Authority: Secs. 1006, 2002(a), 3001, and 3002 of the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act, of 1976, as amended (42 U.S.C. 6905, 6912(a), 6912, and 6922).

2. In Appendix XI, add the following wastestreams in alphabetical order:

Appendix XI—Wastes Excluded Under §§ 260.20 and 260.22.

TABLE 1.—WASTES EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
EPA's Mobile Incineration System.	Denney Farm Site, McDowell, MO.	(a) Wastes excluded from non-specific sources: Process wastewater, rotary kiln ash, CHEAF media, and other solids (except spent activated carbon) (EPA Hazardous Waste Nos. F020, F022, F023, F026, F027, and F028) generated during the field demonstration of EPA's Mobile Incinerator at the Denney Farm Site in McDowell, Missouri, after July 25, 1985, so long as: (1) the incinerator is functioning properly; (2) a grab sample is taken from each tank of wastewater generated and the EP leachate values do not exceed 0.03 ppm for mercury, 0.14 ppm for selenium, and 0.88 ppm for chromium; and (3) a grab sample is taken from each drum of soil or ash generated and a core sample is collected from each CHEAF roll generated and the EP leachate values of daily composites do not exceed 0.044 ppm in ash or CHEAF media for mercury or 0.22 ppm in ash or CHEAF media for selenium.

[FR Doc. 85-17623 Filed 7-24-85; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 10

[CGD 77-084]

Licensing of Pilots; Manning of Vessels—Pilots

AGENCY: Coast Guard, DOT.

ACTION: Final rule; correction of effective date.

SUMMARY: On June 24, 1985, the Coast Guard published a Final Rule at 50 FR 26106 regarding the licensing of pilots, effective July 24, 1985. Section 10.07-9(e) provides that if an individual holding a first class pilot's license or endorsement does not satisfactorily complete a physical examination within 90 days prior to the anniversary date of the issuance of the license, the license or endorsement is invalid as of the anniversary date and the individual may not operate under the authority of that license or endorsement until a physical examination has been completed. The 90 day provision was intended to provide flexibility in scheduling physical examinations in recognition of the employment practices in the merchant marine.

In order to provide sufficient time to schedule and complete a physical examination within 90 days prior to the anniversary date of the issuance of the license without undue hardship to license holders, the effective date for § 10.07-9(e) is delayed to January 1, 1986.

Holders of a pilot license or endorsement with an anniversary date after January 1, 1986, must satisfactorily complete a physical examination within 90 days prior to that anniversary date.

The effective date for the final rule appearing in column one of page 26106 of the Federal Register issue of June 24, 1985, is corrected to read as follows:

EFFECTIVE DATE: July 24, 1985, except for § 10.07-9(e) which is effective January 1, 1986.

FOR FURTHER INFORMATION CONTACT: Mr. John J. Hartke, Office of Merchant Marine Safety (G-MVP/12), Room 1210, U.S. Coast Guard Headquarters, 2100 Second Street, S.W., Washington, D.C. 20593, (202) 426-2985.

Dated: July 23, 1985.

J.W. Kime,

Commodore, U.S. Coast Guard, Chief, Office of Merchant Marine Safety.

[FR Doc. 85-17806 Filed 7-23-85; 4:12 pm]

BILLING CODE 4910-14-M

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 552 and 570

[APD 2800.12 CHGE 12]

General Services Administration Acquisition Regulation; Competition in Contracting Act

Correction

In FR Doc. 85-18048, beginning on page 27589 in the issue of Friday, July 5, 1985, make the following corrections:

1. On page 27590, in the first column, in section 552.270-2, the first word in the tenth line of the GSAR provision should read "offers".

2. On page 27593, in the first column, the number of the last subpart heading in the table of sections for Part 570 should read "570.7".

3. Also on page 27593, in the second column, in section 570.101, the first word in the third line of paragraph (c) should read "interests".

4. On page 27597, in the first column, in section 570.502, the third word in the seventh line of paragraph (b)(3)(ii) should read "firm".

5. On page 27598, in the second column, in section 570.602-2, the fourth word in the eighth line of paragraph (c)(3) should read "of".

BILLING CODE 1505-01-M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 1

[OST Docket No. 1; Amdt. 1-203]

Organization and Delegation of Powers and Duties; Fiscal Year 1985 Interstate Cost Estimate

AGENCY: Office of the Secretary; DOT.

ACTION: Final rule.

SUMMARY: This amendment delegates to the Administrators of the Federal Highway Administration (FHWA) and the Urban Mass Transportation Administration (UMTA) all functions vested in the Secretary by Public Law 98-229 apportioning certain funds for construction of the Interstate Highway System in Fiscal Year 1985 and increasing amounts available for emergency highway relief. These all relate to matters administered by FHWA and UMTA.

DATE: The effective date of this amendment is March 9, 1984.

FOR FURTHER INFORMATION CONTACT: Robert I. Ross, Office of the General Counsel, C-50, Department of Transportation, Washington, DC (202) 426-4723.

SUPPLEMENTARY INFORMATION: Since this amendment relates to Departmental management, procedures, and practice, notice and comment on it are unnecessary and it may be made effective in fewer than thirty days after publication in the *Federal Register*.

This statute approves the Interstate Cost Estimate factors necessary to apportion \$2 billion in Interstate construction funds and approves the Interstate Substitution Cost Estimate factors necessary to apportion \$330 million in Interstate transfer funds for highway and transit projects. Also, it provides an additional \$150 million for fiscal year 1984 in emergency relief highway funds. All of these functions are being delegated to FHWA, except the authority to apportion funds for Interstate substitute transit projects, which is being delegated to UMTA.

List of Subjects in 49 CFR Part 1

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

PART 1—[AMENDED]

In consideration of the foregoing, Part

1 of Title 49, Code of Federal Regulations, is amended as follows:

1. The authority citation for 49 CFR Part 1 continues to read as follows:

Authority: Secs. 3, 9, Department of Transportation Act (49 U.S.C. 1652 and 1657(e)), unless otherwise noted.

2. Section 1.48 is amended by adding a new paragraph (bb), and the introductory text of the section is repeated for the convenience of the reader, to read as follows:

§ 1.48 Delegations to Federal Highway Administrator.

The Federal Highway Administrator is delegated authority to—

(bb) Carry out the functions vested in the Secretary by Pub. L. 98-229, 98 Stat. 55, insofar as it relates to apportioning certain funds for construction of the Interstate Highway System in Fiscal Year 1985, apportioning certain funds for Interstate substitute highway projects, and increasing amounts available for emergency highway relief.

3. Section 1.51 is amended by adding at the end thereof a new paragraph (n), and the introductory text of the section is repeated for the convenience of the reader, to read as follows:

§ 1.51 Delegations to Urban Mass Transportation Administrator.

The Urban Mass Transportation Administrator is delegated authority to exercise the functions vested in the Secretary by:

(n) Section 2 of Pub. L. 98-229, 98 Stat. 55, insofar as it relates to apportioning certain funds for Interstate substitute transit projects.

Issued in Washington, DC, on July 1, 1985.

Elizabeth H. Dole,

Secretary of Transportation.

[FR Doc. 85-17035 Filed 7-24-85; 8:45 am]

BILLING CODE 4910-62-M

INTERSTATE COMMERCE COMMISSION

49 CFR Parts 1000, 1011, 1100, 1101 and 1160

[Ex Parte No. 55 (Sub-55)]

Revision and Redesignation of Rules of Practice; Correction

AGENCY: Interstate Commerce Commission.

ACTION: Final rules; technical amendments.

SUMMARY: At 47 FR 49534, November 1, 1982, the Commission published rules revising and redesignating all of its procedural regulations governing the conduct of formal cases which come before it for decision. That document contained inadvertent errors and omissions which this document corrects by making technical amendments as set forth below:

FOR FURTHER INFORMATION CONTACT:

Kathleen M. King, (202)275-7428.

SUPPLEMENTARY INFORMATION: Title 49 of the CFR Parts 1000, 1011, 1100, 1101 and 1160 are amended as follows:

PART 1000—THE COMMISSION

§ 100.735-19 [Amended]

1. In § 100.735-19, the words "Appendix C of the Rules of Practice of the Commission (Part 1100 of the chapter)" are revised to read "§ 1102.2."

PART 1011—COMMISSION ORGANIZATION; DELEGATIONS OF AUTHORITY

§ 1011.7 [Amended]

2. In § 1011.7(d), the reference to "§ 1133.3(a)" is revised to read "§ 1113.3(b)(1)."

PART 1100—GENERAL PROVISIONS

§ 1100.2 [Amended]

3. In § 1100.2, the reference to "Parts 1100-1119" in the first sentence is corrected to read "Parts 1100-1129."

PART 1101—DEFINITIONS AND CONSTRUCTION

§ 1101.2 [Amended]

4. In § 1101.2, the last sentence in paragraph (b) is revised to read as follows: See 49 CFR Part 1011, Commission Organization; Delegations of Authority.

PART 1160—HOW TO APPLY FOR OPERATING AUTHORITY

§ 1160.61 [Amended]

5. In § 1160.61, the CFR reference in the last sentence of paragraph (a) is revised to read "49 CFR 1104.2."

James H. Bayne,

Secretary.

[FR Doc. 85-17557 Filed 7-24-85; 8:45 am]

BILLING CODE 7035-01-M

Proposed Rules

Federal Register

Vol. 50, No. 143

Thursday, July 25, 1985

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 85-ACE-07]

Proposed Designation of Transition Area—Minneapolis, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This Notice proposes to designate a 700-foot transition area at Minneapolis, Kansas, to provide controlled airspace for aircraft executing a new instrument approach procedure to the Minneapolis City County Airport, Minneapolis, Kansas, utilizing the Salina VORTAC as a navigational aid. This proposed action will change the airport status from VFR to IFR.

DATE: Comments must be received on or before August 30, 1985.

ADDRESSES: Send comments on the proposal to: Federal Aviation Administration, Manager, Operations, Procedures and Airspace Branch, Air Traffic Division, ACE-540, 601 East 12th Street, Kansas City, Missouri 64106, Telephone (816) 374-3408.

The official docket may be examined at the Office of the Regional Counsel, Central Region, Federal Aviation Administration, Room 1558, 601 East 12th Street, Kansas City, Missouri.

An informal docket may be examined at the Office of the Manager, Operations, Procedures and Airspace Branch, Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Dale L. Carnine, Airspace Specialist, Operations, Procedures, and Airspace Branch, Air Traffic Division, ACE-540, FAA, Central Region, 601 East 12th Street, Kansas City, Missouri 64106, Telephone (816) 374-3408.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons may participate in the proposed rulemaking by submitting such written data, views or arguments as they may desire. Communications should identify the airspace docket number, and be submitted in duplicate to the Operations, Procedures and Airspace Branch, Air Traffic Division, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106. All communications received on or before the closing date for comments will be considered before action is taken on the proposed amendment. The proposal contained in this Notice may be changed in light of the comments received. All comments received will be available both before and after the closing date for comments in the Rules Docket for examination by interested persons.

Availability of NPRM

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Operations, Procedures and Airspace Branch, 601 East 12th Street, Kansas City, Missouri 64106, or by calling (816) 374-3408.

Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for further NPRMs should also request a copy of Advisory Circular No. 11-2A which describes the application procedure.

Discussion

The FAA is considering an amendment to Subpart G, § 71.181 of the Federal Aviation Regulations (14 CFR 71.181) by designating a 700-foot transition area at Minneapolis, Kansas. To enhance airport usage, a new instrument approach procedure is being developed for the Minneapolis, Kansas, City County Airport utilizing the Salina VORTAC as a navigational aid. This navigational aid will provide new navigational guidance for aircraft utilizing the airport. The establishment of a new instrument approach procedure based on this navigational aid entails designation of a transition area at Minneapolis, Kansas, at and above 700 feet above ground level within which aircraft are provided air traffic control service. Transition areas are designed to contain IFR operations in controlled airspace during portions of the terminal

operation, and while transiting between the terminal and enroute environment. The intended effect of this action is to ensure segregation of aircraft using the approach procedure under Instrument Flight Rules (IFR), and other aircraft operating under Visual Flight Rules (VFR). This action will change the airport status from VFR to IFR. Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6A, dated January 2, 1985.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Transition areas.

The Proposed Amendment Part 71

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration (FAA) proposes to amend Part 71 of the FAR (14 CFR Part 71) as follows:

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) [Revised Pub. L. 97-449, January 12, 1983]; 14 CFR 11.65.

2. By amending Section 71.181 as follows:

Minneapolis, Kansas

That airspace extending upward from 700 feet above the surface within a 6.5 mile radius of the Minneapolis City County Airport (Latitude 39°05'41"N; Longitude 97°43'13"W); within five miles either side of the Salina, Kansas VORTAC 341° radial extending from 10 NM SE of the airport to the

6.5 mile radius area, excluding that portion which overlies the Salina, Kansas, transition area.

Issued in Kansas City, Missouri, on July 16, 1985.

Edwin S. Harris,

Director, Central Region.

[FR Doc. 85-17611 Filed 7-24-85; 8:45 am]

BILLING CODE 4910-13-M

ENVIRONMENTAL PROTECTION AGENCY

21 CFR Part 561

[FAP OH5275, 3H5378/P369; PH-FRL 2859-5]

Thiodicarb; Proposed Tolerances

Correction

In FR Doc. 85-16086 beginning on page 27452 in the issue of Wednesday, July 3, 1985, make the following corrections:

1. On page 27452, in the second column, under **SUPPLEMENTARY INFORMATION**, in the third paragraph, in the third line, "Methomuy" should read "methomyl".

2. On page 27455, in the second column, in the table, the heading in the third column should read "Sm".

BILLING CODE 1505-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. 85M-0056]

Neurological Devices; Premarket Approval of the Implanted Intracerebral Subcortical Stimulator for Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Proposed rule; opportunity to request change in classification.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the implanted intracerebral/subcortical stimulator for pain relief, a medical device. The agency also is summarizing its proposed findings on: (1) the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the statute's approval requirements, and (2) the benefits to the public from the use of the device. In addition, FDA is announcing an opportunity for interested persons to

request the agency to change the classification of the device based on new information.

DATES: Comments by September 23, 1985; requests for a change in classification by August 9, 1985.

ADDRESS: Written comments or requests for a change in classification are to be submitted to the Docket Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert F. Munzner, Center for Devices and Radiological Health (HFZ-430), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Background

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I, general controls; class II, performance standards; of class III, premarket approval. As a general rule, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295), and devices marketed on or after that date that are substantially equivalent to such devices, have been, or are being, classified by FDA. For the sake of convenience, this preamble refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date as "preamendments devices."

Sections 501(f), 513, and 515(b) of the act (21 U.S.C. 351(f), 360c, and 360e(b)), taken together, establish as a general requirement that a preamendments device that FDA has classified into class III is subject, in accordance with section 515 of the act, to premarket approval. (As an alternative procedure for premarket approval, section 515(f) of the act provides for development of a PDP, the last stage of which is for FDA to declare that a PDP has been completed.) A preamendments class III device may be commercially distributed without a filed PMA or a notice of completion of a PDP until 90 days after FDA's promulgation of a final rule requiring premarket approval for the device. Also, such a device is exempt from the investigational device exemption (IDE) regulations (21 CFR Part 812) until the date stipulated by FDA in the final rule requiring premarket approval for that device. A device that was not in commercial distribution before May 28,

1976, or that has not been found by FDA to be substantially equivalent to such a device, is required to have an approved PMA or a declared completed PDP in effect before it may be marketed.

Section 515(b)(2)(A) of the act provides that a proceeding for the promulgation of a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing: (1) The proposed rule, (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device, (3) an opportunity for the submission of comments on the proposed rule and the proposed findings, and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice either denying the request or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. If FDA does not initiate such a proceeding, section 515(b)(3) of the act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, promulgate a final rule to require premarket approval, or publish a notice terminating the proceeding. If FDA terminates the proceeding, FDA is required to initiate a proceeding to reclassify the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is made final, section 501(f) of the act mandates that a PMA or a notice of completion of a PDP for any such device be filed within 90 days of the date of promulgation of the final rule, or 30 months after final classification of the device, whichever is later. If a PMA or a notice of completion of a PDP for such a device is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or a notice of

completion of a PDP has not been filed, and there is not any IDE in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334). Shipment of the device in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333).

The act does not permit an extension of the 90-day period after promulgation of a final rule within which an application or notice is required to be filed. The House Report on the amendments states that "the thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval." H. Rept. 94-853, 94th Cong., 2d Sess. 42 (1976).

Classification of the Implanted Intracerebral/Subcortical Stimulator for Pain Relief

In the Federal Register of September 4, 1979 (44 FR 51772), FDA issued a final rule (21 CFR 882.5840) classifying the implanted intracerebral/subcortical stimulator for pain relief into class III. The preamble to the proposal to classify the device (43 FR 55720; November 28, 1978) included the recommendation of the Neurological Devices Panel (formerly the Neurological Device Section of the Respiratory and Nervous System Devices Panel) (the Panel), an FDA advisory committee, regarding the classification of the device. The Panel's recommendation included a summary of the reasons the device should be subject to premarket approval and identified certain risks to health presented by the device. The Panel also recommended under section 513(c)(2)(A) of the act that a high priority for the application of section 515 of the act be assigned to the implanted intracerebral/subcortical stimulator for pain relief. The preamble to the final rule classifying the device advised that the earliest date by which a PMA for the device (or a notice of completion of a PDP) could be required was May 28, 1982, or 90 days after promulgation of a rule requiring premarket approval for the device, whichever occurred later.

In the Federal Register of September 6, 1983 (48 FR 40272), FDA published a notice of intent to initiate proceedings to require premarket approval of 13 preamendments class III devices

assigned a high priority by FDA for the application of premarket approval requirements. Among other things, the notice describes the factors FDA takes into account in establishing priorities for initiating proceedings under section 515(b) of the act for promulgating final rules requiring that preamendments class III devices have approved PMA's or declared completed PDP's. Using these factors, FDA has determined that the implanted intracerebral/subcortical stimulator for pain relief, identified in § 882.5840(a), has a high priority for initiating a proceeding to require premarket approval. Accordingly, FDA is commencing a proceeding under section 515(b) of the act to require that the implanted intracerebral/subcortical stimulator for pain relief have an approved PMA or a PDP that has been declared completed.

Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is proposing to require that a PMA or a notice of completion of a PDP be filed with the agency for the implanted intracerebral/subcortical stimulator for pain relief within 90 days after promulgation of any final rule based on this proposal. An applicant whose device was in commercial distribution before May 28, 1976, or has been found by FDA to be substantially equivalent to such a device, will be permitted to continue marketing the implanted intracerebral/subcortical stimulator for pain relief during FDA's review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 days, of the date of filing. FDA cautions that under section 515(d)(1)(B)(i) of the act, FDA may not enter into an agreement to extend the review period for a PMA unless the agency finds that " * * * the continued availability of the device is necessary for the public health."

FDA intends that, under § 812.2(d), the preamble to any final rule based on this proposal will stipulate that as of the date on which a PMA or notice of completion of a PDP is required to be filed, the exemptions in § 812.2(c) (1) and (2) from the requirements of the IDE regulations for preamendments class III devices will cease to apply to any implanted intracerebral/subcortical stimulator for pain relief: (1) Which is not legally on the market on or before that date or (2) which is legally on the market on or before that date but for which a PMA or notice of completion of a PDP is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA or a notice of completion of a PDP for the implanted intracerebral/subcortical stimulator for pain relief is not filed with FDA within 90 days after the date of promulgation of any final rule requiring premarket approval for the device, commercial distribution of the device will be required to cease. The device may be distributed for investigational use only if the requirements of the IDE regulations regarding significant risk devices are met. The requirements for significant risk devices include submitting an IDA application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued. FDA, therefore, cautions that IDE applications should be submitted to FDA at least 30 days before the end of the 90-day period to avoid interrupting investigations.

Description of Device

The implanted intracerebral/subcortical stimulator for pain relief is a device that applies electrical current to subsurface areas of the brain to treat severe intractable pain. The device consists of an implanted radiofrequency (RF) receiver, electrodes that are placed within the brain, a pocket-sized external RF transmitter, and an external coil (antenna). The RF pulses are transmitted via the antenna through the skin to the subcutaneously placed RF receiver, which converts the RF energy to electrical impulses. The impulses are delivered via lead wires to the electrodes in the brain.

The electrodes are implanted in the brain through a burr hole in the skull. The receiver is implanted under the skin through an incision. A tunnel is made beneath the skin to accommodate the lead wires that extend from the receiver to the electrodes.

Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the implanted intracerebral/subcortical stimulator for pain relief to have an approved PMA or a declared completed PDP, and (2) the benefits to the public from the use of the device.

Degree of Risk

Damage to neural tissue. The electrical current used for stimulation and the presence of the electrode may cause injury to brain tissue. Charge densities used to treat patients cannot

be determined from published reports of clinical studies. Animal studies indicate that by using low charge densities, electrical injury to brain tissue can be minimized. Mortimer et al. studied the effects of electrical stimulation on the blood brain barrier of cats and concluded that the upper limit for safe stimulation is 0.05 watt per square inch when biphasic electrical pulses are used (Ref. 24). Pudenz investigated the degree of neural damage caused by electrically stimulating the cerebral cortex of cats. The author found that some amount of neural damage is consistently produced if the charge per phase of the stimulus pulse is 0.45 microcoulomb (μC) or greater (Ref. 27). Recently, Yuen et al. found that neural damage in the cerebral cortex of cats increased proportionally as the charge density per phase increased over the range of 40 to 400 μC per square centimeter per phase (Ref. 39).

Two authors have published studies of autopsy material taken from patients who had been implanted with deep brain stimulators. Gybels et al. reported on a series of five cancer patients who were followed for 2 weeks to 17 months (average 7 months) after implantation (Ref. 14). All patients showed histological reactions to the electrode, including necrosis, mesenchymal reactions, glial reactions, and inflammatory reactions with giant cells. Three of the five patients were autopsied after 6 to 17 months, and showed chromatolysis of neurones in the target area and mild gliosis. These histological reactions were attributed to chronic stimulation. Boivie and Meyerson reported pathological findings in a group of five cancer patients autopsied 3 weeks to 17 months after implantation (Ref. 8). In four of these patients, small lesions resembling old infarcts were observed along the electrode tracks. The lesions were characterized by slight gliosis and mild neuronal reactions extending 0.5 to 0.7 millimeter (mm) beyond the track. A thin fibrous sheath surrounded the electrode tracks in three of the four patients. The results of the very small studies by Gybels et al. (Ref. 14) and by Boivie and Meyerson (Ref. 8) indicate that histological reaction to the presence of the electrodes may be mild. These studies, however, reported findings on a total of only 10 patients.

Several undesirable neurological effects have been reported in patients treated with deep brain stimulation. Dieckmann and Witzmann reported lesions in the target points in 3 of 46 patients (7 percent) (Ref. 12). Coagulated brain tissue was removed with an electrode from a fourth patient. The

authors attribute their finding to "inappropriate" (i.e., continuous) stimulation by the patients. Richardson and Akil, in their study of long-term effects of stimulation of the periventricular gray matter, reported fogging of blurring of vision in five of eight patients (63 percent) (Ref. 33). In a second series of 30 patients, these same authors reported emotional changes, vertigo, and hemiparesis in 7 patients (23 percent) (Ref. 31). Munding and Salamao reported oculomotor or other undesirable paresthesias and focal seizures in 3 of 32 patients (9 percent) (Ref. 25). Plotkin reported contralateral paresthesias in 1 of 48 patients (2 percent) which persisted even after removal of the electrodes (Ref. 26). Ray and Burton reported major motor seizures in 1 of 28 patients (4 percent) (Ref. 28).

Surgical complications. Implantation of the device requires two operations. In the first one, burr holes are cut into the skull under the local anesthetic. Electrodes are inserted stereotactically through the holes in the skull and placed into selected areas of the brain (target points). X-rays are used to verify the placement of the electrodes. The wires from the electrodes extend through the scalp and are attached directly to the stimulator. If the stimulation is not effective when current is applied, the electrodes are moved to target points that are effective. Alternatively, new electrodes may be inserted. When effective stimulation is achieved, a second operation is performed under general anesthesia to implant the receiver and the lead wires.

Complications may occur because of these surgical procedures. Because implantation surgery involves the brain, the complications are usually serious. Inserting an electrode into the brain can puncture blood vessels. Intraventricular hemorrhage has been reported in up to 5 percent of patients (Refs. 12, 17, 25, and 28). Several authors have reported infections, including meningitis, in 3 to 4 percent of their patients (Refs. 2, 12, 17, and 26). Richardson and Akil, however, reported meningitis in 3 of 30 patients (10 percent) (Ref. 31). An additional patient in this group had an "infected device." Ray and Burton, in a series of 22 patients, reported 1 death during surgery, but did not give any information about the rate of infection (Ref. 28).

Electrode migration. Implanted electrodes can spontaneously move from their original position, or they can be dislodged by a blow to the head. Electrode movement may cause damage to brain tissue or produce stimulation of other areas of the brain which may

result in undesirable neurological effects. Additional surgical procedures may be required to remove and replace or to reposition electrodes that have moved from the original target points.

Several authors have reported electrode migration in 2 to 17 percent of their patients (Refs. 2, 12, 17, 25, 26, 28, 31, 33, and 37). Turnbull et al. reported electrode dislodgement in 3 of 18 patients (17 percent) (Ref. 37). In one of these patients, dislodgement resulted in aberrant motor responses, permanent sensory deficits, and seizures.

Tolerance. Tolerance to stimulation may develop (Refs. 17, 23, 26, and 31) and has been reported to occur in 30 percent of patients in whom the device was implanted (Ref. 35). Such patients require ever-increasing periods of stimulation to relieve their pain. Continuous stimulation has been reported to cause damage to brain tissue (Ref. 20).

Patients who become tolerant to deep brain stimulation will also demonstrate tolerance to pharmacological opiates. When such tolerance occurs, the patient will not be able to relieve his or her pain with electrical stimulation or with narcotic analgesics. There is evidence, however, that discontinuance of stimulation for a period of time in conjunction with oral administration of L-tryptophan may reverse this tolerance (Refs. 18, 19, 28, 30, and 35).

Skin erosion. Erosion of the skin can occur in the scalp over the area where the electrodes exit from the cranium or can occur over the site of the receiver.

Erosion has been stated by Shiner to be a significant problem (Ref. 35). Adams and Hosobuchi consider erosion of hardware through the scalp to be the most troublesome source of infection (Ref. 2). They reported that scalp erosion necessitated removal of the entire device in 3 of 39 patients (8 percent).

Cerebrospinal fluid leakage. Cerebrospinal fluid (CSF) may leak out where electrode wires pass through the dura. CSF leakage is a risk common to devices implanted in the central nervous system (Refs. 10, 11, and 20). CSF leakage requires reoperation to correct the condition.

Tissue toxicity. The surface material of the implanted receiver, lead wires, or electrodes may not be biocompatible. There have not been any reports of patient injuries due to improper materials used in the device. Although the types of materials used in the device are generally thought to be biocompatible, it is possible that contaminants may be introduced during the manufacture of the device, or that some of the materials may have

unknown constituents that can cause subtle changes that have not been recognized in the reported studies.

Benefits of the Device

The implanted intracerebral/subcortical stimulator for pain relief has been reported to provide relief from peripheral chronic pain syndromes resulting from carcinomas, failed low backs, nerve entrapments, and phantom limb syndromes (Refs. 8, 14, 17, 25, 26, 28, 31, 32, 35, and 37). Cooper et al. treated six patients and reported that deep brain stimulation may reverse chronic neurologic deficits such as hemiparesis, dystonia, torticollis, tremor, speech impairments, and epilepsy (Ref. 9). Heath et al. reported using up to 125 stainless steel or silver ball electrodes per patient in 75 patients with schizophrenia, epilepsy, depression, Parkinson's disease, narcolepsy, and intractable pain of various etiologies; clinical results, however, were not discussed (Ref. 15).

Some investigators have reported successful treatment of pain of central origins, e.g., thalamic syndromes, brain stem infarction, and spinal cord injury (Refs. 25 and 32). Other authors, however, have concluded that the device is probably not beneficial in treating central pain (Refs. 26, 29, and 39).

The most frequently used stimulation targets are the periventricular gray region near the posterior wall of the third ventricle, the periaqueductal gray region, and the sensory nuclei of the thalamus. Following the discovery that naloxone would reverse stimulation-produced analgesia, Akil et al. demonstrated that endogenous opiates are released into the fluid of the third ventricle following stimulation of the periventricular gray region (Refs. 6 and 7). Further, Hosobuchi et al. demonstrated a 50 to 300 percent increase in β -endorphins with stimulation of the periaqueductal gray region (Ref. 18).

Although electrical stimulation of both the periaqueductal gray and periventricular gray matter appears to produce opiate-mediated analgesia, stimulation in these areas may produce unpleasant or intolerable side effects. For example, Richardson and Akil observed that stimulation of periaqueductal gray matter may produce feelings of smothering, blurred vision, nausea, or vertigo (Refs. 30, 32, and 33). Thoden et al. discovered that stimulation of the medial thalamus may produce unpleasant paresthesias, headache, increased pain, or nausea (Ref. 36). Some researchers have reported pain relief with stimulation

within the internal capsule (Refs. 2, 3, and 17), although there is not any indication that endogenous opiates are produced when this area is stimulated (Refs. 18, 23, and 38).

Reports on the incidence of beneficial effects from electrical stimulation of the brain vary greatly. Success rates of 70 to 80 percent were reported in studies conducted by Richardson and Akil (Ref. 33), Plotkin (Ref. 26), Turnbull et al. (Ref. 37), Mundinger and Salamao (Ref. 25), and Ray and Burton (Ref. 28), whereas Gybels reported only one "good" result in eight patients (Ref. 13). Gybels et al. later reported one "good" result in a series of five patients (Ref. 14). Criteria for assessing patient improvement are not consistent from study to study, and many authors do not describe patient evaluation methods. For these reasons, the success rates reported in various studies may not be comparable.

It has been shown that the location of the stimulating electrode is critical (Ref. 1), and it was initially suggested that the discrepancy between Gybels' results in five patients (Ref. 14) and the results reported in other studies could be explained by small differences in electrode position. However, Gybels et al. obtained autopsy material from the five patients on which they reported in 1980 (Ref. 14). Anatomical and pathological examinations revealed that the electrodes were accurately positioned in the target points in four of these five patients; yet only one of the five patients had obtained good pain relief during the study.

Patient selection. Patient selection is an important factor in predicting benefit from the implanted intracerebral/subcortical stimulator for pain relief. Several investigators used a morphine saturation test to screen potential patients. Plotkin reports that if morphine produces analgesia in a patient, and naloxone reverses the effect, there is a good probability that the patient will benefit from deep brain stimulation (Ref. 26). Plotkin's report of successful treatment of 38 of 48 patients tends to support this position. Seven of the 10 patients whose treatment was unsuccessful had not been screened by the morphine test. When they were tested after failing at deep brain stimulation, the responses of all seven patients indicated that they were not good candidates for the procedure.

Discussion of Risks and Benefits

The electrodes of the implanted intracerebral/subcortical stimulator for pain relief have to penetrate the brain. Published reports indicate that there is a substantial risk of hemorrhage which could result in death or physical

disruption of brain tissue. In turn, such disruption could result in permanent neurological deficits such as seizures, hemiparesis, visual impairment, emotional changes, nausea, vertigo, or undesirable paresthesias. Meningitis has been reported as a serious complication of the procedure. Migration of the electrodes from the original target area can render the device ineffective and may damage other brain tissue. As a result, additional surgery may be required to replace, remove, or reposition the electrodes.

It cannot be determined from the published literature whether the stimulation current being applied with the device is safe for neural tissue. Coagulation of brain tissue and production of lesions in target points have been reported to be the result of continuous electrical stimulation with the intracerebral/subcortical stimulator for pain relief.

Although several authors have attempted to explain the highly variable clinical results obtained with the device, the question of the effectiveness of the device has not been resolved (Refs. 8 and 14). Animal studies have revealed a number of areas in the brain which could produce analgesia (Refs. 1, 4, 5, 21, and 22). Published reports, however, indicate that there is not any consensus as to which target point, when stimulated, will provide the best pain relief. Meyerson reports that the medio-basal part of the posterior thalamus is the preferred site (Ref. 23). Thoden et al. prefer the medial thalamus (Ref. 36). Plotkin and others have found that periventricular gray matter provides the best pain relief (Refs. 12, 26, 30, and 33). Adams and Hosobuchi have used the internal capsule (Ref. 2). Hosobuchi now favors use of the periaqueductal gray matter (Ref. 18), even though Richardson concluded in 1977 that stimulation of this area produced noxious and intolerable side effects (Ref. 30).

Plotkin as well as Richardson has concluded that pain secondary to the damaged central nervous system or deafferentation (e.g., thalamic syndromes) does not respond well to deep brain stimulation (Refs. 26 and 29). Adams, however, reports that thalamic or pseudothalamic syndrome or paraplegia pain is relieved by this treatment (Ref. 3). Two investigators reported effective treatment of conditions other than intractable chronic pain with deep brain stimulation (Refs. 6 and 7). These findings have not been reported by others.

FDA believes that use of the implanted intracerebral/subcortical stimulator carries a significant risk of

hemorrhage and permanent damage to brain tissue which can result in permanent, debilitating, or fatal neurological complications. This risk appears to be inherent in the implantation procedure. Damage to brain tissue caused by the stimulating current has been reported, and FDA believes that proper stimulation parameters for the device have not been established. Damage to brain tissue also has been reported as a result of electrode migration. Although two small studies, each with five patients, indicate that histological damage resulting from the physical presence of the electrode may be minor, FDA believes that additional pathological data are required to determine the probable extent of tissue reaction.

Published reports indicate that the implanted intracerebral/subcortical stimulator may provide pain relief for selected patients, but that the device may not be suitable for treating certain patients or all types of pain. FDA believes that additional data are required to explain the variable clinical results obtained to date with the device.

FDA classified the implanted intracerebral/subcortical stimulator for pain relief into class III because insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide such assurance. FDA has weighed the probable benefits to health from the use of the device and believes that the studies discussed throughout this document present evidence of significant risks associated with the use of the device and raise questions about whether probable benefits from use of the device outweigh the risk of illness or injury from such use. Accordingly, FDA believes that the implanted intracerebral/subcortical stimulator for pain relief should undergo premarket approval to establish conditions of use that will minimize risks to patients and to determine whether the risks of using the device are balanced by the benefits to the patient.

Opportunity to Request a Change in Classification

Before requiring the filing of a PMA or a notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(iv) of the act and § 860.132 of FDA's regulations governing classification of devices (21 CFR 860.132) to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. The legal standard

governing reclassification under section 513(e) of the act and § 860.123 is discussed in detail in the preambles to FDA's proposed rules to reclassify daily wear spherical contact lenses consisting of rigid gas permeable plastic materials and daily wear optically spherical (soft) contact lenses from class III into class I (47 FR 53402, 53411; November 26, 1982).

A request for a change in the classification of the implanted intracerebral/subcortical stimulator for pain relief is to be in the form of a reclassification petition containing the information required by § 860.123, including new information relevant to the classification of the device, and shall, under section 515(b)(2)(B) of the act, be submitted by August 9, 1985.

The agency advises that to assure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in classification of the implanted intracerebral/subcortical stimulator for pain relief is submitted, the agency will by September 23, 1985, after consultation with the appropriate FDA advisory committee and by an order published in the Federal Register, either deny the request or give notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the act and § 860.130 of the regulations.

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The following references have been placed on file in the Dockets Management Branch (address above) and may be reviewed by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an

environmental assessment nor an environmental impact statement is required.

Economic Impact

FDA has examined the economic consequences of this proposed rule in accordance with the criteria in section 1(b) of Executive Order 12291 and has found that the proposal would not be a major rule as specified in the Order. The agency believes that only three small firms will be affected by this proposed rule. Therefore, the agency certifies under the Regulatory Flexibility Act (Pub. L. 96-354) that the proposed rule would not have a significant economic impact on a substantial number of small entities. An assessment of the economic impact of any final rule based on this proposal has been placed on file in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Part 882 be amended as follows:

PART 882—NEUROLOGICAL DEVICES

1. The authority citation for 21 CFR Part 882 is revised to read as follows:

Authority: Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 380c, 371(a)); 21 CFR 5.10; §§ 882.5820(c) and 882.5840(c) also issued under secs. 501, 515, 520(g), 52 Stat. 1049-1050 as amended, 90 Stat. 552-559, 569-571 (21 U.S.C. 351, 360e, 360(g)).

2. In § 882.5840 by adding a new paragraph (c), to read as follows:

§ 882.5840 Implanted intracerebral/subcortical stimulator for pain relief.

(c) *Date premarket approval application (PMA) or notice of completion of a product development protocol (PDP) is required.* A PMA or a notice of completion of a PDP is required to be filed with FDA on or before (date to be 90 days after date of promulgation of final rule) for any implanted intracerebral/subcortical stimulator for pain relief that was in commercial distribution before May 28, 1976, or that has on or before (date to be 90 days after date of promulgation of final rule) been found to be substantially equivalent to an implanted intracerebral/subcortical stimulator for

pain relief that was in commercial distribution before May 28, 1976. Any other implanted intracerebral/subcortical stimulator for pain relief shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Interested persons may, in or before September 23, 1985, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Interested persons may, on or before August 9, 1985, submit to the Dockets Management Branch written requests to change the classification of the implanted intracerebral/subcortical stimulator for pain relief. Two copies of any requests are to be submitted, except that individuals may submit one copy. Comments or requests are to be identified with the docket number found in brackets in the heading of this document. Received comments and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 26, 1985.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 85-17652 Filed 7-24-85; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 950

Proposed Modifications to the Wyoming Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Reopening of public comment period.

SUMMARY: OSM is reopening the period for review and comment on modified portions of the Wyoming permanent regulatory program. On November 28, 1984 (49 FR 46755), OSM announced a public comment period and procedures for requesting a public hearing on the substantive adequacy of a proposed amendment to the Wyoming permanent regulatory program under the Surface Mining Control and Reclamation Act of