(B) Two sets of printed copies of any revised labeling to be placed in use, identified with the new animal drug application number; and

(C) A statement by the applicant that all promotional labeling and all new animal drug advertising will promptly be revised consistent with the changes made in the labeling on or within the new animal drug package no later than upon approval of the supplemental application.

(iv) If the supplemental application is not approved, FDA may order the manufacturer to cease distribution of the drug under the proposed labeling.

(4) *Changes providing for additional distributors to be reported under Records and reports concerning experience with new animal drugs for which an approved application is in effect (§ 514.80)*[2]. Supplemental applications as described under paragraph (c)(2) of this section will not be required for an additional distributor to distribute a drug that is the subject of an approved new animal drug application if the conditions described under § 514.80(a)(2), (b)(3), and (b)(5)(iii) are met.

(d) *Patent information*. The applicant shall comply with the patent information requirements under section 512(c)(3) of the act.

(e) *Claimed exclusivity*. If an applicant claims exclusivity under section 512(c)(2)(F) of the act upon approval of a supplemental application for a change in its previously approved new animal drug product, the applicant shall include such a statement.

(f) *Good laboratory practice for nonclinical laboratory studies*. A supplemental application that contains nonclinical laboratory studies shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

11. Section 514.106 is amended by removing paragraph (b)(1)(xiv) and by revising paragraphs (b)(1)(vi) and (b)(1)(xiii) to read as follows:

§ 514.106 Approval of supplemental applications.

* * * * *

(b) * * *

(1) * * *

(vi) A change in promotional material for a prescription new animal drug not exempted by § 514.8(c)(2)(i)(C)(*3*).

* * * * *

(xiii) A change permitted in advance of approval as described under § 514.8(b)(3).

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

12. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.5 [Amended]

13. Section 558.5 *New animal drug requirements for liquid Type B feeds* is amended in paragraph (e) by removing ''514.8(d) and (e)'' and by adding in its place ''514.8(c)(3)''.

Dated: June 23, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–25493 Filed 9–30–99; 8:45 am]

BILLING CODE 4160–01–F

[2] See footnote 1.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 99N-2099]

General Hospital and Personal Use Devices; Classification of the Subcutaneous, Implanted, Intravascular Infusion Port and Catheter and the Percutaneous, Implanted, Long-term Intravascular Catheter

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify the subcutaneous, implanted, intravascular (IV) infusion port and catheter, and the percutaneous, implanted, long-term catheter intended for repeated vascular access into class II (special controls). The agency is also publishing the recommendations of FDA's General Hospital and Personal Use Devices Panel (the panel) regarding the classification of these devices. After considering public comments on the proposed classification, FDA will publish a final regulation classifying these devices. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices.

DATES: Written comments by December 30, 1999. See section IX of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia M. Cricenti, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval). Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will ensure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance.

The SMDA broadened the definition of class II devices to mean those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance. Special controls may include performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendment devices, are classified after FDA has met the following three requirements: (1)

FDA has received a recommendation from a device classification panel (an FDA advisory committee); (2) FDA has published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) FDA has published a final regulation classifying the device. FDA has classified most preamendment devices under these procedures. Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendment devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations. A preamendment device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

In 1980, when other general hospital and personal use devices were classified (45 FR 69678, October 21, 1980), FDA was not aware that two vascular access devices intended for repeated vascular access, the subcutaneous, implanted, IV infusion port and catheter and the percutaneous, implanted, long-term IV catheter were preamendments devices, and inadvertently omitted classifying them.

II. Device Identifications

FDA is proposing the following device identifications based on the panel's recommendations (Ref. 1) and the agency's review:

(1) A subcutaneous, implanted, intravascular infusion port and catheter is a device that consists of a subcutaneous, implanted reservoir that connects to a long-term intravascular catheter. The device allows for repeated access to the vascular system for the infusion of fluids and medications and the sampling of blood. The device consists of a portal body which houses a resealable septum with an outlet made of metal, plastic, or a combination of these materials and a long-term intravascular catheter that is either preattached to the port or attached to the port at the time of device placement. The device is available in various profiles and sizes and can be of a single or multiple lumen design.

(2) A percutaneous, implanted, long-term intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings, such as luer hubs, and accessories that facilitate the placement of the device, such as a stylet or guide wire. The device allows for repeated access to the vascular system for long-term use of 30 days or more for administration of fluids, medications, and nutrients; the sampling of blood; and the monitoring of blood pressure and temperature. The device may be made of metal, rubber, plastic, composite materials, or any combination of these materials and may be of single or multiple lumen design.

III. Recommendations of the Panel

During a public meeting held on March 11, 1996, the panel unanimously recommended that the subcutaneous, implanted, IV infusion port and catheter and the percutaneous, implanted, long-term IV catheter be classified into class II (special controls) (Ref. 1). The panel also recommended that two existing FDA guidance documents, ''Guidance on 510(k) Submissions for Implanted Infusion Ports'' (Ref. 2) and ''Guidance Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters'' (Ref. 3), and prescription use of the devices by practitioners licensed by law to use the devices (§ 801.109 (21 CFR 801.109)) be the special controls for the devices.

IV. Summary of the Reasons for the Recommendations

The panel concluded that the safety and effectiveness of the subcutaneous, implanted, IV infusion port and catheter and the percutaneous, implanted, long-term IV catheter could be reasonably assured by special controls in addition to general controls. The panel also believed that sufficient information exists to establish special controls to provide such assurance, specifically the existing premarket notification guidances and prescription use labeling of the devices.

V. Risks to Health

After considering the panel's deliberations, as well as the published literature and medical device reports, FDA has evaluated the risks to health associated with the use of the subcutaneous, implanted, IV infusion port and catheter and the percutaneous, implanted, long-term IV catheter. FDA now believes the following are risks to health associated with the use of the devices:

A. Infection

Infection is the most significant complication associated with the use of venous access devices. Infection occurs in 5 to 30 percent of the patients implanted with the device, depending on the patient's diagnosis, the type of device used, and the criteria used to establish the presence of an infection (Refs. 4 through 7 and 13 through 24).

B. Occlusion

Occlusion may result from clot formation inside the lumen of the catheter, precipitate formation inside the port or catheter from incompatible drugs, or from catheter tip placement against a vein wall or valve. An occluded catheter lumen may lead to infection, thromboembolism, and propagation of the clot, which may cause venous thrombosis. Proper flushing techniques can prevent some causes of occlusion, and thrombolytic therapy can successfully clear most catheter occlusions (Refs. 11 through 13 and 17 through 24).

C. Thrombophlebitis

Thrombophlebitis occurs in 12.5 to 23 percent of patients implanted with the devices (Refs. 5 through 11 and 20 through 23). The incidence varies with the patient population.

D. Pneumothorax

Pneumothorax is the presence of air within the thoracic cavity. The incidence, secondary to procedural or device-related complications, is believed to be up to 5 percent, depending on the manner in which the venous system is accessed (Refs. 8 through 12 and 19 through 24).

E. Other Risks to Health

Less frequent complications associated with the use of vascular access devices include the following: Catheter malposition; migration and inadequate anchoring; hemorrhage; vessel trauma, including puncture, laceration and erosion of vessel and the skin; catheter pinch-off (compression of the catheter between the clavicle and the first rib); and drug extravasation (leakage) (Refs. 4 through 24).

VI. Summary of Data Upon Which the Recommendation is Based

In addition to the potential risks of the subcutaneous and percutaneous implanted vascular access systems described in section V of this document, there is reasonable knowledge of the benefits of the devices. Specifically,

these long-term implanted devices provide convenient, reliable access to the vascular system while requiring less maintenance than alternative vascular access devices, and they improve the quality of life of patients (Refs. 8 through 11, 18 through 20, and 24).

Based on the available information, FDA believes that existing premarket notification guidance documents are adequate special controls capable of providing reasonable assurance of the safety and effectiveness of the subcutaneous, implanted, IV infusion port and catheter and the percutaneous, implanted, long-term IV catheter with regard to the identified risks to health of these devices. The panel also recommended including the prescription statement (§ 801.109) as a special control. Because the prescription statement is already required by § 801.109, FDA believes it is unnecessary to list prescription labeling as a separate special control for these devices.

VII. Special Controls

In addition to general controls, FDA agrees with the panel that the identified premarket notification guidance documents ''Guidance on 510(k) Submissions for Implanted Infusion Ports'' (Ref. 2) and ''Guidance on 510(k) Submission for Short-Term and Long-Term Intravascular Catheters'' (Ref. 3) are appropriate special controls to address the risks to health described in section V of this document. The premarket notification guidance documents address the following: (1) Practitioner labeling, (2) patient labeling, (3) biocompatibility testing, (4) mechanical testing, (5) clinical data requirement, and (6) sterilization procedures.

In order to receive these guidance documents via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number followed by the pound sign (#). For ''Guidance on 510(k) Submissions for Implanted Infusion Ports,'' the document number is 392. For ''Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters,'' the document number is 824. Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidances may also do so using the World Wide Web (WWW). The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

A. Practitioner Labeling

The practitioner labeling section of the premarket notification guidance documents can help control the risks of infection; occlusion; thrombophlebitis; pneumothorax; catheter malposition, migration and improper/or inadequate anchoring; catheter pinch-off; drug extravasation; and septum leakage by having the manufacturer provide information on the following: (1) Indications for use, including patient and device selection; (2) contraindications for use in patients with known or suspected infections, allergies, and intolerance to implant materials; (3) warnings and precautions; (4) identification, prevention, and treatment of complications; (5) directions for use, including preparation of the patient, preparation of the device, site selection, implant procedure, postoperative care, and different use applications (bolus infusion, continuous infusion, blood sampling, and monitoring of blood pressure and temperature).

B. Patient Labeling

The patient labeling section of the premarket notification guidance documents can help control the risks of infection; occlusion; thrombophlebitis; pneumothorax; catheter malposition, migration and improper anchoring; catheter pinch-off; drug extravasation; septum leakage; vessel trauma, including puncture, laceration and erosion of vessel; and erosion of the skin by having the manufacturer provide prospective patients information on the following: (1) Device description and use; (2) implantation procedure; (3) care of the implant site; and (4) minimization, recognition, and treatment of complications.

C. Biocompatibility Testing

Adherence to the biocompatibility testing section of the premarket notification guidance documents can control the risk of adverse tissue reaction by having the manufacturer demonstrate that the patient contacting materials of the subcutaneous, implanted, IV infusion port and catheter, and the percutaneous, implanted, long-term IV catheter are safe for long-term implantation.

D. Mechanical Testing

Adherence to the mechanical testing section of the premarket guidance documents can help control the risk of erosion of the blood vessel and the skin; catheter occlusion and migration; leaking catheter to catheter and/or catheter to port connections; and septum and port leakage.

E. Clinical Data Requirements

For subcutaeous, implanted, IV infusion port and catheters and percutaneous, implanted, long-term IV catheters that appear to be significantly different from devices already on the market, the clinical data section of the premarket guidance documents can help control the risks to health associated with the use of the devices by assuring that these devices are safe and effective for their intended uses.

F. Sterilization Procedures and Labeling

Adherence to sterilization procedures and labeling section of the premarket notification guidances can help control the risk of infection by guarding against the implantation of an unsterile device and providing information on the proper maintenance of an implanted device.

VIII. Proposed Classification

FDA concurs with the panel's recommendations that the subcutaneous, implanted, IV infusion port and catheter and the percutaneous, implanted, long-term IV intended for repeated vascular access should be classified into class II (special controls). FDA believes that the special controls described in section VII of this document, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the devices, and there is sufficient information to establish special controls to provide such assurance.

IX. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its publication in the **Federal Register.**

X. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

XI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. As unclassified devices, these devices are already subject to premarket notification and the general labeling provisions of the act. FDA, therefore, believes that classification in class II with premarket notification guidance and labeling guidance as special controls will impose no significant economic impact on any small entities. The Commissioner therefore certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

XII. Submission of Comments

Interested persons may, on or before December 30, 1999, 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. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

XIII. References

The following references have been placed on display 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:

1. General Hospital and Personal Use Devices Panel, thirtieth meeting, transcript, March 11, 1996.

2. ''Guidance on 510(k) Submissions for Implanted Infusion Ports,'' FDA, October 1990.

3. ''Guidance Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters,'' FDA, March 1995.

4. Abi-Nader, J., ''Peripherally Inserted Central Venous Catheters in Critical Care Patients,'' *Heart & Lung*, 22:428–433, 1993.

5. Aitken, D., and J. Minton, ''The 'Pinch-Off Sign': A Warning of Impending Problems With Permanent Subclavian Catheters,'' *American Journal of Surgery*, 148:633–636, 1984.

6. Broviac, J.W., J. J. Cole, and B. A. Scribner, ''A Silicone Rubber Atrial Catheter for Prolonged Parenteral Alimentation,'' *Surgery, Gynecology and Obstetrics*, 136:602–606, 1973.

7. Brown, J., ''Peripherally Inserted Central Catheters—Use in Home Care,'' *Journal of Intravenous Nursing*, 12:144–150, 1989.

8. Camp-Sorrell, D., ''Implantable Ports,'' *Journal of Intravenous Nursing*, 15:262–273, 1992.

9. Chathas, M. K., J. B. Paton, and D. E. Fisher, ''Percutaneous Central Venous Catherization,'' *American Journal of Diseases of Children, 144: 1246–1250, 1990.*

10. Girvan, D. P., L. L. deVeber, M. J. Inwood, and E. A. Clegg, ''Subcutaneous Infusion Ports in the Pediatric Patient with Hemophilia,'' *Journal of Pediatric Surgery*, 29:1220–1223, 1994.

11. Harvey, M. P., R. J. Trent, D. E. Joshua, G. Ramsey-Stewart, D.W. Storey, and M. Kronenberg, ''Complications Associated with Indwelling Venous Hickman Catheters in Patients with Hematological Disorders,'' *Australian and New Zealand Journal of Medicine*, 16:211–215, 1986.

12. Hickman, R. O., C. D. Buckner, and R. A. Clift, ''A Modified Right Atrial Catheter for Access to the Venous System in Marrow Transplant Recipients,'' *Surgery, Gynecology and Obstetrics*, 148:871–875, 1979.

13. Hoppe, B., ''Central Venous Catheter-related Infections: Pathogenesis, Predictors, and Prevention,'' *Heart & Lung*, 24:333–339, 1995.

14. International Standards Organization (ISO) 1055-1, Sterile, Single Use Intravascular Catheter, Part 2: Central Venous Catheters.

15. Kahn, M. L., R. Barboza, G. A. Kling, and J. E. Heisel, ''Initial Experience with Percutaneous Placement of the PAS Port Implantable Venous Access Device,'' *Journal of Vascular and Interventional Radiology*, 3:459–461, 1992.

16. Laffer, U., M. During, H. R. Bloch, and J. Landmann, ''Surgical Experiences with 191 Implanted Venous Port-a-Cath Systems,'' *Cancer Research*, 121:189–197, 1991.

17. Lawson, M., ''Partial Occlusion of Indwelling Central Venous Catheters,'' *Journal of Intravenous Nursing*, 14:157–159, 1991.

18. Lokich, J. J., A. Bothe, P. Benotti, and C. Moore, ''Complications and Management of Implanted Venous Access Catheters,'' *Journal of Clinical Oncology*, 3:710–717, 1985.

19. McKee, J., ''Future Dimensions in Vascular Access,'' *Journal of Intravenous Nursing*, 14:387–393, 1991.

20. Merrell, S. W., B. G. Peatross, M. D. Grossman, J. J. Sullivan, and W. G. Harker, ''Peripherally Inserted Central Venous Catheter: Low-risk Alternatives for Ongoing Venous Access,'' *Western Journal of Medicine*, 160:25–30, 1994.

21. Morris, P., R. Buller, S. Kendall, and B. Anderson, ''A Peripherally Implanted Permanent Central Venous Access Device,'' *Obstetrics & Gynecology*, 78:1138–1142, 1991.

22. Reed, W. P., K. A. Newman, and J. C. Wade, ''Choosing an Appropriate Implantable Device for Long-Term Venous Access,'' *European Journal of Cancer Clinical Oncology*, 25:1383–1391, 1989.

23. Ryder, M. A., ''Peripherally Inserted Central Venous Catheters,'' *Nursing Clinics of North America*, 28:937–971, 1993.

24. Scott, W. L., ''Complications Associated with Central Venous Catheters,'' *Chest*, 94:1221–1224, 1988.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend part 880 to read as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 880.5965 is added to subpart F to read as follows:

§ 880.5965 Subcutaneous, implanted, intravascular infusion port and catheter.

(a) *Identification*. A subcutaneous, implanted, intravascular infusion port and catheter is a device that consists of a subcutaneous, implanted reservoir that connects to a long-term intravascular catheter. The device allows for repeated access to the vascular system for the infusion of fluids and medications and the sampling of blood. The device consists of a portal body with a resealable septum and outlet made of metal, plastic, or combination of these materials and a long-term intravascular catheter is either preattached to the port or attached to the port at the time of device placement. The device is available in various profiles and sizes and can be of a single or multiple lumen design.

(b) *Classification*. Class II (special controls) Guidance Document: ''Guidance on 510(k) Submissions for Implanted Infusion Ports.''

3. Section 880.5970 is added to subpart F to read as follows:

§ 880.5970 Percutaneous, implanted, long-term intravascular catheter.

(a) *Identification*. A percutaneous, implanted, long-term intravascular catheter is a device that consists of a

slender tube and any necessary connecting fittings, such as luer hubs, and accessories that facilitate the placement of the device. The device allows for repeated access to the vascular system for long-term use of 30 days or more, and it is intended for administration of fluids, medications, and nutrients; the sampling of blood; and monitoring blood pressure and temperature. The device may be constructed of metal, rubber, plastic, composite materials, or any combination of these materials and may be of single or multiple lumen design.

(b) *Classification*. Class II (special controls) Guidance Document: ''Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters.''

Dated: September 24, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–25554 Filed 9–30–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

RIN 1010–AC56

Producer-Operated Outer Continental Shelf Pipelines That Cross Directly into State Waters

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Proposed rule.

SUMMARY: This proposed rule would clarify some unresolved regulatory issues involving the 1996 memorandum of understanding on Outer Continental Shelf pipelines between the Departments of the Interior and Transportation. It would primarily address producer-operated pipelines that do not connect to a transporting operator's pipeline on the OCS before crossing into State waters. It is complementary to the final rule published on August 17, 1998, that addressed producer-operated oil or gas pipelines that connect to transporting operators' pipelines on the Outer Continental Shelf. The proposed rule also would set up procedures for producer and transportation pipeline operators to get permission to operate under either MMS or Department of Transportation regulations governing pipeline design, construction, operation, and maintenance according to their operating circumstances.

DATES: MMS will consider all comments we receive by November 30, 1999. We will begin reviewing comments then and may not fully consider comments we receive after November 30, 1999.

ADDRESSES: Mail or hand-carry comments to the Department of the Interior; Minerals Management Service; Mail Stop 4020; 381 Elden Street; Herndon, Virginia 20170–4817; Attention: Rules Processing Team.

Mail or hand-carry comments with respect to the information collection burden of the proposed rule to the Office of Information and Regulatory Affairs; Office of Management and Budget; Attention: Desk Officer for the Department of the Interior (OMB control number 1010–NEW); 725 17th Street, N.W., Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Carl W. Anderson, Operations Analysis Branch, at (703) 787–1608; e-mail carl.anderson@mms.gov.

SUPPLEMENTARY INFORMATION:

Background

MMS, through delegations from the Secretary of the Interior, has authority to issue and enforce rules to promote safe operations, environmental protection, and resource conservation on the Outer Continental Shelf (OCS). (The Outer Continental Shelf Lands Act (43 U.S.C. 1331 *et seq.*) defines the OCS). Under this authority, MMS regulates pipeline transportation of mineral production and rights-of-way for pipelines and associated facilities. MMS approves all OCS pipeline applications, regardless of whether a pipeline is built and operated under Department of the Interior (DOI) or Department of Transportation (DOT) regulatory requirements. MMS also has sole authority to grant rights-of-way for OCS pipelines. MMS administers the following laws as they relate to OCS pipelines:

(1) the Federal Oil and Gas Royalty Management Act of 1982 (FOGRMA) for oil and gas production measurement, and

(2) the Federal Water Pollution Control Act, as amended by the Oil Pollution Act and implemented under Executive Order (E.O.) 12777. (Under a February 3, 1994, Memorandum of Understanding (MOU) to better define their responsibilities under the Oil Pollution Act, DOI, DOT, and the U.S. Environmental Protection Agency divided their responsibilities for oil spill prevention and response according to the definition of ''coastline'' in the Submerged Lands Act, 43 U.S.C. 1301(c) (59 FR 9494–9495).) Nothing in this rule will affect MMS's authority under either FOGRMA or the Oil Pollution Act.

The May 6, 1976, Memorandum of Understanding

A May 6, 1976, MOU between DOI and DOT, MMS regulated oil and gas pipelines located upstream of the ''outlet flange'' of each facility where produced hydrocarbons were first separated, dehydrated, or otherwise processed. A result of this arrangement was that downstream (generally shoreward) of the first production platform where processing takes place, DOT-regulated pipelines crossed MMS-regulated facilities. Because of incompatible regulatory requirements, this arrangement was not satisfactory for either agency.

The December 10, 1996, Memorandum of Understanding

In the summer of 1993, MMS and DOT's Research and Special Programs Administration (RSPA) renewed their negotiations that resulted in the MOU of December 1996. In May 1995, MMS and RSPA published a **Federal Register** Notice proposing to revise the 1976 MOU and scheduling a public meeting on the proposal (60 FR 27546–27552). Under the MOU, as proposed in the joint notice:

> The DOI area of responsibility will extend from producing wells to 50 meters (164 feet) downstream from the base of the departing pipeline riser on the last OCS production or processing facility. * * * Additionally, DOI will have responsibility for the following pipelines:
>
> a. That portion of a pipeline otherwise subject to DOT responsibility that crosses an OCS production or processing facility from 50 meters upstream of the base of the incoming riser to 50 meters downstream of the base of the [departing] riser. * * *

Succeeding paragraphs described various other arrangements involving the 50-meter regulatory boundary. The notice included an illustrated appendix to assist readers in interpreting various situations under which either DOI or DOT regulatory responsibility would apply.

Commenters on the May 1995 notice found the proposed 50-meter regulatory boundary to be unsatisfactory for two reasons. First, the boundary was not tied to an identifiable valve or other device that could isolate any pipeline segment under consideration. Second, the boundary was submerged and inaccessible to both operators and the regulatory agencies.

MMS and RSPA soon agreed to ask a joint industry workgroup representing OCS oil and natural gas producers and transmission pipeline operators to recommend a solution for defining regulatory boundaries.