Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 175.300 [Amended]

2. Section 175.300 *Resinous and polymeric coatings* is amended in paragraph (b)(3)(xxxiii), under the entry ''5-Chloro-2-methyl * * *'', by removing ''(CAS Reg. No. 2628–20–4)'' and adding in its place ''(CAS Reg. No. 2682–20–4)''.

3. Section 175.320 is amended in the table in paragraph (b)(3) by revising the entry under item (iii) for ''5–Chloro-2-methyl-4-isothiazolin-3-one'' under the headings ''List of substances'' and ''Limitations'' to read as follows:

§ 175.320 Resinous and polymeric coatings for polyolefin films.

* * * * *

(b) * * *

(3) * * *

List of substances	Limitations
* * * * * * *	
(iii) Adjuvants (release agents, waxes, and dispersants):	
* * * * * * *	
5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172–55–4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682–20–4) mixture, at a ratio of 3 parts to 1 part, respectively, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935–90–2) and optionally containing magnesium nitrate (CAS Reg. No. 10377–60–3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight).	For use only as an antimicrobial agent in emulsion-based silicone coatings at a level not to exceed 50 milligrams per kilogram (based on isothiazolone active ingredient) in the coating formulation.
* * * * * * *	

* * * * *

Dated: June 7, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–14905 Filed 6–12–00; 8:45 am]

BILLING CODE 4160–01–F

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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the subcutaneous, implanted, intravascular (IV) infusion port and catheter, and the percutaneous, implanted, long-term IV catheter intended for repeated vascular access into class II (special controls). This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices.

DATES: This rule is effective July 13, 2000.

FOR FURTHER INFORMATION CONTACT: M. Patricia 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. Background

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 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 preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments 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: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with 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 preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Consistent with the act and the regulations, FDA consulted with the General Hospital and Personal Use Devices Panel (the Panel), an FDA advisory committee, regarding the classification of these devices.

II. Regulatory History of the Devices

In the **Federal Register** of October 1, 1999 (64 FR 53294), FDA issued a proposed rule to classify the subcutaneous, implanted, IV infusion port and catheter, and the percutaneous, implanted, long-term IV catheter intended for repeated vascular access into class II. Interested persons were given until December 30, 1999, to comment on the proposed regulation.

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

FDA received one comment from a manufacturer who concurred with the proposed rule to classify the devices into class II. FDA agrees with the comment.

III. Summary of Final Rule

Based on the Panel's recommendation (Ref. 1), FDA is classifying the subcutaneous, implanted, IV infusion port and catheter and the percutaneous, implanted, long-term IV catheter intended for repeated vascular access into class II. FDA has determined that existing premarket notification FDA guidance documents, ''Guidance on 510(k) Submissions for Implanted Infusion Ports'' (Ref. 2) and ''Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters'' (Ref. 3) are adequate special controls capable of providing reasonable assurance of safety and effectiveness with regard to the identified risks to health of these devices. The Panel also recommended including the prescription statement (§ 801.109 (21 CFR 801.109)) as a special control. Because this prescription statement is already required by § 801.109, FDA believes it is unnecessary to list prescription labeling as a special control for these devices.

IV. Summary of the Reasons for the Recommendations

Therefore, under section 513 of the act, FDA is adopting the summary of reasons for the Panel's recommendation and the summary of data upon which the Panel's recommendation is based (Ref. 1), and it is also adopting the assessment of the risks to public health stated in the proposed rule published on October 1, 1999. Furthermore, FDA is issuing this final rule which classifies the generic types of devices, the subcutaneous, implanted, IV infusion port and catheter, and the percutaneous, implanted, long-term IV catheter intended for repeated vascular access into class II.

V. 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.

VI. Analysis of Impacts

FDA has examined the impacts of the final 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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 guidances as special controls will impose no significant economic impact on any small entities. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final 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.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. These references 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 on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters,'' FDA, March 1995.

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, 21 CFR part 880 is amended 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,'' FDA October 1990.

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: May 23, 2000.

Linda S. Kahan,

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

[FR Doc. 00–14698 Filed 6–12–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 206

RIN 1010–AC09

Approved Publications and Tables for Use in Applying Revised Royalty Valuation Regulations for Federal Oil

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of approved publications.

SUMMARY: As required by revised Federal oil valuation regulations, the Minerals Management Service (MMS) has approved three spot price publications that royalty payors should use to value oil produced from Federal leases not sold at arm's length.

EFFECTIVE DATE: June 1, 2000.

ADDRESSES: See **FOR FURTHER INFORMATION CONTACT** section below.

FOR FURTHER INFORMATION CONTACT: David Domagala, Royalty Valuation Division, Royalty Management Program, Minerals Management Service, P.O. Box 25165, Mail Stop 3151, Denver, Colorado 80225, telephone number (303) 275–7255 or fax number (303) 275–7227.

SUPPLEMENTARY INFORMATION: MMS published its revised regulations establishing oil value for royalty due on Federal leases in the **Federal Register** on March 15, 2000 (65 FR 14022), effective June 1, 2000. The primary changes in the revised regulations affect Federal lessees who value oil not sold at arm's length. The rule provides that the primary means of valuing crude oil not sold at arm's length is an adjusted spot price, except in the Rocky Mountain Region, where use of an adjusted spot price for valuation purposes is the third valuation benchmark (30 CFR 206.103(b)(4))(65 FR 14091). The applicable spot price is the one for the oil most closely representing the lease production in terms of physical proximity and quality parameters. The lessee may select the spot price from any MMS-approved publication; however, once the lessee selects a publication for a geographical area (California/Alaska, the Rocky Mountain Region, or the rest of the country), it must continue to use that same publication for 2 years in that area.

In § 206.104 of the final rule (65 FR 14092) for establishing oil value for royalty due on Federal leases, MMS explained that ''approved publications'' must be:

(1) Publications buyers and sellers frequently use;

(2) Publications frequently mentioned in purchase or sales contracts;

(3) Publications that use adequate survey techniques, including development of spot price estimates based on daily surveys of buyers and sellers of Alaska North Slope (ANS) and other crude oil; and

(4) Publications independent from MMS, other lessors, and lessees.

Additionally, MMS established that:

(1) Any publication may petition MMS to be added to the published list of acceptable publications.

(2) MMS will reference the tables a lessee must use in the approved publications to determine the associated index prices.

(3) MMS may revoke its approval of a particular publication if it determines that the prices published in the publication do not accurately represent spot market values.

MMS has verified that the publications listed below meet approval criteria based on input from staff of the publication itself, as well as information from marketers, auditors and industry consultants. MMS also examined and compared historical published spot prices from all three of the approved publications to ensure comparability and consistency. The approved publications and applicable tables are as follows:

- *Platt's Oilgram Price Report* (The same spot prices appear in *Platt's Global Alert, Platt's Crude Oil Marketwire,* and the soon-to-be-published *Platt's U.S. Crudewire.*) Use the spot prices found in the ''Crude Price Assessments'' section.
- *Petroleum Argus Americas Crude* (The same spot prices appear in *Argus Crude, Argus Americas Crude Datafile, Argus Crude Datafile.*) Use the spot prices found in the ''WTI Cushing,'' ''US Gulf Coast,'' ''US Midcontinent,'' and ''US West Coast'' sections.
- *Bloomberg Oil Buyers Guide Petroleum Price Supplement* (The same spot prices appear on the *Bloomberg Energy Web Site,* and in *Bloomberg Professional.*) Use the spot prices found in the ''Worldwide Crude Price Snapshot'' section.

If any of these entities use identical spot price quotes in other of their publications or distributions (such as electronic bulletin boards, newsletters, etc.), they are also approved. MMS will