The California ISO notes that, under Order No. 641, annual charge assessments can be recovered from transmission customers as a legitimate cost of providing transmission service, but that the specifics of such recovery are left to be addressed by individual public utilities in case-by-case filings with the Commission.[30] The California ISO explains that, because there is uncertainty as to the level of annual charges to be assessed against each individual public utility, and therefore uncertainty as to the design of an appropriate cost-recovery mechanism, the Commission should clarify that individual public utilities may recover annual charges in transmission rates from transmission customers even if there is some uncertainty as to the level of annual charges being assessed against those public utilities, and that annual charges assessed by the Commission may, in turn, be recovered in transmission rates in the year that the charges are billed to those public utilities (even though the annual charges assessed by the Commission are developed using data that reflects the prior year's transactions).[31] The California ISO adds that, as a revenue-neutral, not-for-profit entity that passes through all of its costs to the market participants that use the transmission system it operates, there is a special need for clarification, and that, in the first year that the new annual charge methodology is used, there is likewise a special need for clarification.[32] The California ISO also commits to modify any annual charge cost-recovery mechanism that it proposes ''as needed to prevent over- or under-recovery of such costs once it receives the initial assessment of annual charges under the new methodology.'' [33]

The Commission explained, in Order No. 641, that the purpose of Order No. 641 was to change the methodology by which the Commission assessed annual charges to public utilities, and that the issue of the rate recovery of annual charge assessments by the public utilities to whom they were assessed was a different issue and outside the scope of Order No. 641. The Commission noted that it already had in place regulations that address rate recovery of utility costs, *i.e.,* Part 35 of its regulations, but added that, to allay public utility concerns, it would state in Order No. 641 that the annual charges assessed by the Commission were ''costs that can be recovered in transmission rates as a legitimate cost of providing transmission service.'' [34]

We reaffirm those determinations here. We also note that our regulations provide great flexibility in how public utilities may develop their rates, including their transmission rates. Our regulations provide that rates may be based on data for historical periods, such as the so-called Period I test period, and that rates may also be based on data for future periods, such as the so-called Period II test period.[35] We thus have long allowed rates to be based on estimates, as long as the estimates were reasonable when made.[36] This flexibility is sufficient, we believe, to allow public utilities like the California ISO to recover in their transmission rates for the first year under the new annual charges methodology adopted in Order No. 641, *i.e.,* calendar year 2002, the annual charges that will be assessed by the Commission in that same year, *i.e.,* calendar year 2002 (even though those charges are calculated from transactions that occurred during the preceding year, calendar year 2001).[37] To this extent, therefore, we clarify Order No. 641.

The Commission Orders

PSE&G's request for rehearing is hereby denied, and the California ISO's request for clarification is hereby granted in part, as discussed in the body of this order.

By the Commission.

David P. Boergers,

Secretary.

[FR Doc. 01–7001 Filed 3–20–01; 8:45 am]

BILLING CODE 6717–01–P

[30] California ISO Clarification at 1–2.

[31] *Id.* at 2, 7–8, 11–13. In the alternative, the California ISO objects to Order No. 641 in the absence of additional information concerning the level of annual charges that will be assessed under Order No. 641. *Id.* at 2, 7, 8–11. As noted earlier, annual charges are intended to recover the Commission's collectible electric regulatory program costs (*i.e.,* its total electric regulatory program costs, less any electric filing fees and less the costs of regulating the PMAs). Under Order No. 641, these collectible electric regulatory program costs will now be recovered from public utilities based on transmission volumes (rather than, as in the past, both power sale and transmission volumes). To the extent that the California ISO's pleading may be construed as seeking rehearing of Order 641, its arguments are addressed in the discussion earlier concerning PSE&G's similar arguments.

[32] *Id.* at 6–7, 12.

[33] *Id.* at 12

[34] Order No. 641, FERC Stats. & Regs. at 31,857.

[35] *See* 18 CFR 35.13. *Accord, e.g.,* Revised Requirements for Filing Changes in Electric Rate Schedules, Order No. 91, 45 FR 46,352 (July 10, 1980), FERC Stats. & Regs. Regulations Preambles 1977–1981 ¶ 30,170 at 31,146–48 (1980), *reh'g denied,* Order No. 91–A, 12 FERC ¶ 61,206 (1980).

[36] *E.g.,* New England Power Company, Opinion No. 379, 61 FERC ¶ 61,331 at 62,217 & n.62 (1992), *reh'g denied,* Opinion No. 379–A, 65 FERC ¶ 61,036 (1993), *aff'd,* 53 F.3d 377, 380 (D.C. Cir. 1995); Southern California Edison Company, Opinion No. 359, 53 FERC ¶ 61,408 at 62,415 & n.22 (1990), *reh'g denied,* Opinion No. 359–A, 54 FERC ¶ 61,320 (1991).

[37] Particularly given the California ISO's commitment to modify any annual charge cost-recovery mechanism that it proposes as needed to prevent over- or under-recovery of such costs once it receives the initial assessment of annual charges under this new methodology. *See supra* note 33 and accompanying text.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 00P–1554]

Medical Device; Exemption From Premarket Notification; Class II Devices; Pharmacy Compounding Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order granting a petition requesting exemption from the premarket notification requirements for pharmacy compounding systems classified within the intravascular administration set, with certain limitations. This rule will exempt from premarket notification pharmacy compounding systems classified within the intravascular administration set and establishes a guidance document as a special control for this device. FDA is publishing this order in accordance with the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This rule is effective March 21, 2001.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Public Law 101–629)), devices are to be classified

into class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976, (generally referred to as postamendments devices) are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations (21 CFR part 807) require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that 1 day after date of publication of the list under section 510(m)(1) of the act, FDA may exempt a device on its own initiative, or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance that the agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff.'' That guidance can be obtained through the Internet on the CDRH home page at http://www.fda.gov/cdrh or by facsimile through CDRH Facts-on-Demand at 1–800–899–0381 or 301–827–0111. Specify ''159'' when prompted for the document shelf number.

III. Petition

On October 3, 2000, FDA received a petition requesting an exemption from premarket notification for pharmacy compounding systems classified within the intravascular administration set. Pharmacy compounding systems are currently classified under 21 CFR 880.5440 as an intravascular administration set. In the **Federal Register** of December 15, 2000 (65 FR 78494), FDA published a notice announcing that this petition had been received and provided opportunity for interested persons to submit comments on the petition by January 16, 2001. FDA received two comments opposing an exemption from premarket notification for these devices.

These comments objected that these devices presented risks to the patient, who may receive an inaccurate formula due to programming errors. One comment pointed out that the American Society of Hospital Pharmacists (ASHP) recommended that pharmacists should verify that a device they intend to use is cleared by FDA in a 510(k) as evidence of compliance with regulatory requirements. One comment further stated ''Class I device exemption would eliminate the requirement for reporting changes in device design, manufacturing and quality control systems for FDA review prior to implementation under the provisions of 21 CFR 807.81(3)(i).'' Both comments objected that the petitioner did not establish that the device met FDA criteria for exemption from premarket notification.

FDA disagrees with these comments. These devices will remain in Class II and will be subject to general controls other than premarket notification such as labeling requirements and the quality systems regulation. In addition, in this rule, FDA is establishing a guidance document entitled ''Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA Reviewers'' as a special control for this device. This guidance document will address the remaining regulatory requirements for these devices. FDA believes that the remaining general controls and the guidance document will address any risks to health, such as programming errors, presented by these devices. This exemption is limited to the pharmacy compounding system as described, and is also subject to the general limitations on exemptions from premarket notification for therapeutic devices as described in 21 CFR 880.9. Therefore, manufacturers will have to submit premarket notifications for any changes that bring the device outside of the exempt category. FDA does not believe that maintaining a requirement for premarket notification is necessary to ensure compliance with the ''existing requirements'' referenced in the ASHP publication.

FDA has determined that pharmacy compounding systems classified within the intravascular administration set meet the criteria for exemption from the notification requirements. FDA believes that the requirements outlined in the guidance document will provide reasonable assurance of the safety and effectiveness of these devices.

IV. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA Reviewers'' via your fax machine, call the CDRH Facts-on-Demand system at 800–899–0381 or 301–827–0111 from a touchtone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1326) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request. Persons interested in

obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes, ''Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA Reviewers,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at www.fda.gov/cdrh.

V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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. Because this rule will relieve a burden and simplify the marketing of these devices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. 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.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rules 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.

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 880.5440 is amended by revising paragraph (b) to read as follows:

§ 880.5440 Intravascular administration set.

* * * * *

(b) *Classification.* Class II (special controls). The special control for pharmacy compounding systems within this classification is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Pharmacy Compounding Systems; Final Guidance for Industry and FDA Reviewers.'' Pharmacy compounding systems classified within the intravascular administration set are exempt from the premarket notification procedures in subpart E of this part and subject to the limitations in § 880.9.

Dated: March 12, 2001.

Linda S. Kahan,

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

[FR Doc. 01–6938 Filed 3–20–01; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP Western Alaska–01–001]

RIN 2115–AA97

Safety Zone; Gulf of Alaska, southeast of Narrow Cape, Kodiak Island, AK

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule; Correction.

SUMMARY: The Coast Guard published in the **Federal Register** of March 19, 2001, a document establishing a temporary safety zone in the Gulf of Alaska, southeast of Narrow Cape, Kodiak Island, Alaska. The effective date of the safety zone has changed from March 23, 2001 to March 22, 2001. This correction changes that date.

DATES: This temporary final rule is effective on March 22, 2001.

ADDRESSES: The public docket for this rulemaking is maintained by Coast Guard Marine Safety Office Anchorage, 510 ''L'' Street, Suite 100, Anchorage, AK 99501. Materials in the public docket are available for inspection and copying at Coast Guard Marine Safety Office Anchorage. Normal office hours are 7:30 a.m. to 4 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: LCDR Rick Rodriguez, Marine Safety Office Anchorage, at (907) 271–6700.

SUPPLEMENTARY INFORMATION: The Coast Guard published a document, in the **Federal Register** of March 19, 2001 (66 FR 15350) establishing a temporary safety zone in the Gulf of Alaska, southeast of Narrow Cape, Kodiak Island, Alaska, effective March 23, 2001. The effective date has changed to March 22, 2001 due to a late revision of the rocket launch date. This correction changes the beginning effective date of March 23, 2001 to March 22, 2001.

§ 165.T17–012 [Corrected]

In rule FR Document 01–6740 published on March 19, 2001 (66 FR 15350) make the following corrections. On page 15350, in the 2nd column under *Background and Purpose,* remove the date ''March 23, 2001'' and add the