without losing their small business eligibility for Federal Government procurement.

(b) Objectives and Legal Basis for the Proposed Rule

SBA's objective is to define ''small refiner'' better and to enable small businesses to participate in more and larger Federal Government procurement opportunities. Section 3(a) of the Small Business Act (15 U.S.C. 632(a)) gives SBA the authority to establish and change size standards.

(c) Description and Estimate of the Number of Small Entities To Which the Rule Will Apply

SBA estimates that there will be no more than two newly designated small businesses. Because SBA does not propose to change the 1,500 employee size standard, refiners will only gain eligibility if they have less than 155,000 bpcd as well as no more than 1,500 employees. With regard to refiners that have capacities in excess of 75,000 bpcd, SBA described in the **SUPPLEMENTARY INFORMATION** that it based its estimate of number of employees on 10Ks filed with the Securities and Exchange Commission, Annual Reports and other information available to the public.

Refiners that currently have less than 75,000 bpd capacities are unaffected by this proposed rule, except to the extent that they may take advantage of opportunities arising from this rule. Also, SBA does not believe there will be significantly increased competition that could harm small or other than small business refiners. On the contrary, small businesses will be able to bid on more and larger Federal procurements in a fashion much like the largest refiners, though on a smaller scale, proportionate to their sizes.

Federal procurement programs are voluntary, and this proposed rule, if adopted, will not impose any significant costs on any small business companies participating in Federal procurement programs. Further, the rule will, if adopted, not affect the amount of refined petroleum purchased by the Federal Government. Federal Government procurement dollars are expected to remain about the same. Since SBA estimates that no more than two refiners, not now small, could become eligible, they would have little impact on the distribution of total Federal procurement dollars. Furthermore, the two refiners are not currently participating in Federal procurement, according to FPDC data. In addition, since more smaller refiners will be able to share resources, they will be eligible for more Federal procurement dollars. However, given that all small refiners combined will still only account for 7.7 percent of total U.S. refining capacity, the impact on larger refiners will be negative but negligible, though it will be a positive and significant one on small refiners.

(d) Imposition of Additional Reporting or Recordkeeping Requirements on Small Businesses

This rule does not impose any new information collection requirements on small refiners or other small businesses, and therefore will impose none that could require approval by OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501–3520. The proposed new size standard does not impose any additional reporting, record keeping or compliance requirements on small entities. Increasing the petroleum refiners' capacity size standard expands access to Federal Procurement programs that assist small businesses, but does not impose a regulatory burden as they neither regulate nor control business behavior.

(e) Relevant Federal Rules That May Duplicate, Overlap or Conflict With This Rule

This rule does not duplicate, overlap or conflict with any other Federal rules. This rule applies to the Federal Government's procurement of refined petroleum products only, and does not apply to any other Federal program for which a refiner would have to qualify as a small business.

(f) Alternatives That SBA Considered

SBA considered three alternatives to this rule, namely deleting the capacity requirement in its entirety, and capacities above and below 155,000 bpcd. SBA explains in the **SUPPLEMENTARY INFORMATION** above why it opted to propose 155,000 bpcd rather than another amount or none at all. SBA specifically asks for comments on each of these alternatives, however, and will consider an alternative if public comments support one of them in lieu of the proposed 155,000 bpcd.

List of Subjects in 13 CFR Part 121

Administrative practice and procedure, Government procurement, Government property, Grant programs-business, Loan programs-business, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated in the preamble, SBA proposes to amend 13 CFR part 121 as follows:

PART 121—SMALL BUSINESS SIZE REGULATIONS

1. The authority citation for Part 121 is revised to read as follows:

Authority: Pub L. 105–135 sec. 601 *et seq.*, 111 Stat. 2592; 15 U.S.C. 632(a), 634(b)(6), 637(a), 638, 644(c), and 662(5); and Sec. 304, Pub. L. 103–403, 108 Stat. 4175, 4188.

2. In § 121.201, under Subsector 324, the entry for NAICS Code 324110 is republished and footnote 4 is revised to read as follows:

§ 121.201 What size standards has SBA identified by North American Industry Classification System Codes?

* * * * *

NAICS codes	NAICS description (N.E.C. = not elsewhere classified)	Size standard in number of employees or millions of dollars
*	*	*
324110	Petroleum Refineries	[4]1,500
*	*	*

Footnotes

* * * * *

[4] *NAICS code 324110*—For purposes of Federal Government procurement, the petroleum refiner must be a concern that has no more than 1,500 employees nor more than 155,000 barrels per calendar day total Operable Atmospheric Crude Oil Distillation capacity. Capacity includes owned or leased facilities as well as facilities under a processing agreement or an arrangement such as an exchange agreement or a throughput. The total product to be delivered under the contract must be at least 90 percent refined by the successful bidder from either crude oil or bona fide feedstocks.

* * * * *

Dated: November 1, 2001.

Hector V. Barreto,

Administrator.

[FR Doc. 02–3344 Filed 2–11–02; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 868

[Docket No. 01N–0576]

Medical Devices; Reclassification of the Cutaneous Carbon Dioxide ($PcCO_2$) and the Cutaneous Oxygen (PcO_2) Monitor

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the cutaneous carbon dioxide ($PcCO_2$) monitor from class II (performance standards) into class II (special controls). FDA is also proposing to reclassify the cutaneous oxygen (PcO_2) monitor for an infant patient who is not under gas anesthesia from class II (performance standards) into class II (special controls) and is reproposing the reclassification of the cutaneous oxygen (PcO_2) monitor for all other uses from class III (premarket approval) into class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance document entitled ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Draft Guidance for Industry and FDA'' which would serve as the special control if this proposal becomes final.

These reclassifications are being undertaken on the agency's own initiative based on new information under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997.

DATES: Submit written or electronic comments on the proposed rule by April 15, 2002. See section IV of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Docket Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: William A. Noe, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609, ext. 174.

SUPPLEMENTARY INFORMATION:

I. Background

A. Cutaneous Carbon Dioxide ($PcCO_2$) Monitor

In the **Federal Register** of July 25, 1988 (53 FR 27878), FDA issued for public comment the recommendation of the Anesthesiology and Respiratory Therapy Devices Panel that FDA reclassify the cutaneous carbon dioxide ($PcCO_2$) monitor from class III into class II. On December 9, 1988, FDA sent to all known manufacturers of the device a letter (order) that classified the cutaneous carbon dioxide monitor, and substantially equivalent devices of this generic type, from class III to class II. In the **Federal Register** of June 28, 1989 (54 FR 27160), FDA published a final rule reclassifying the cutaneous carbon dioxide monitor from class III (premarket approval) into class II (performance standards) and added new 21 CFR 868.2480 *Cutaneous carbon dioxide ($PcCO_2$) monitor*.

B. Cutaneous Oxygen (PcO_2) Monitor

In the **Federal Register** of November 2, 1979 (44 FR 63292), FDA published a proposal to classify 149 anesthesiology devices, including the cutaneous oxygen monitor (§ 868.2500). In the **Federal Register** of July 16, 1982 (47 FR 31130), FDA published a final rule classifying the cutaneous oxygen monitor into either class II or class III, depending on the intended use of the device. The cutaneous oxygen monitor intended for use in monitoring infant patients who are not under gas anesthesia was classified as class II (performance standards). This action was based on FDA's belief that there was sufficient data to show the device is safe and effective for this use and that a performance standard would provide reasonable assurance of safety and effectiveness of the device. The final rule also classified into class III the cutaneous oxygen monitor intended for all other uses, that is, in a noninfant patient or in any patient, including an infant, who is under gas anesthesia

In the **Federal Register** of August 14, 1995 (60 FR 41984 and 41986), FDA published two orders for certain class III devices requiring the submission of safety and effectiveness information in accordance with the preamendments class III strategy for implementing section 515(i) of the act (21 U.S.C. 360e(i)), and providing deadlines for submission of the information. In response to that notice, on October 21, 1996, Radiometer Medical A/S submitted a request for reclassification of the cutaneous oxygen monitor for use in noninfant patients not under gas anesthesia.

In the **Federal Register** of March 15, 1999 (64 FR 12774), FDA published a proposed rule to reclassify 38 preamendments class III devices into class II and to establish special controls for these devices. Among the 38 preamendments devices was the cutaneous oxygen monitor intended for all uses other than in an infant patient who is not under gas anesthesia. An American Society for Testing and Materials standard was proposed as the special control. FDA invited interested persons to comment on the proposed rule by June 14, 1999. FDA received six comments and two requests for extension of the comment period for certain devices. One of the requests for extension of the comment period was from a manufacturer of the cutaneous oxygen monitor. The manufacturer recently withdrew this request. None of the comments addressed the cutaneous oxygen monitor.

In the **Federal Register** of March 31, 2000 (63 FR 17138), FDA published a final rule reclassifying 28 of the 38 devices for which it had proposed reclassification. FDA reopened the comment period for 6 of the 38 devices (Vascular graft prosthesis of less than 6 millimeters diameter, 21 CFR 870.3450; Pacemaker lead adapter, 21 CFR 870.3620; Annuloplasty ring, 21 CFR 870.3800; Cardiopulmonary bypass defoamer, 21 CFR 870.4230; Cardiopulmonary bypass arterial blood line filter, 21 CFR 870.4260; and Cardiopulmonary bypass oxygenator, 21 CFR 870.4350) for which it had proposed reclassification and intends to reopen the comment period for 3 other devices in the near future. The remaining of the 38 preamendments devices is the cutaneous oxygen monitor. FDA is, in this notice, reproposing the reclassification of the cutaneous oxygen monitor for all other uses from class III (premarket approval) into class II (special controls).

II. Proposed Rule

FDA is proposing to reclassify the cutaneous carbon dioxide ($PcCO_2$) monitor and the cutaneous oxygen (PcO_2) monitor intended for use in monitoring infant patients who are not under gas anesthesia, from class II (performance standards) into class II (special controls).

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 assure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance. 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, including 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 (21 U.S.C. 360c(a)(1)(B)). At the time the cutaneous carbon dioxide ($PcCO_2$) monitor and the cutaneous oxygen (PcO_2) monitor intended for use in monitoring infant patients who are not under gas anesthesia were classified, 1987 and 1982 respectively, special controls were not a regulatory option. FDA has now developed a draft guidance and is proposing to make it the special control for these products.

FDA is also reproposing the reclassification of the cutaneous oxygen monitor for all other uses from class III (premarket approval) into class II (special controls). In the original March 15, 1999, proposal, FDA had announced its tentative determination that classification into class II with four consensus standards as the special controls would provide reasonable assurance of the safety and effectiveness of the cutaneous oxygen monitor. The agency received no comments on the proposed reclassification of the cutaneous oxygen monitor. Under the SMDA authority, FDA is now proposing a guidance document as the special controls.

FDA is identifying the guidance document entitled ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Draft Guidance for Industry and FDA'' that would serve as the special control for the cutaneous oxygen (PcO_2) monitor for both intended uses and for the cutaneous carbon dioxide ($PcCO_2$) monitor, if this proposal becomes final.

The draft guidance document sets forth the information FDA believes should be included in a 510(k) for these devices. FDA has identified the following as the risks to health presented by these devices (first column of the table below). The second column identifies the portions of the guidance document that address these risks to health. FDA believes that addressing these risks to health in a 510(k) in the manner identified in the guidance document, or an acceptable alternative, is necessary to provide reasonable assurance of the safety and effectiveness of these devices.

TABLE 1.

Identified Risk	Recommended Mitigation Measures
Electrical Shock	Electrical Safety Standards
Electromagnetic Interference	Electromagnetic Compatibility Standards
Toxicity Tissue Reactivity	Biocompatibility and Sterility Guidance
Burns	Biocompatibility and Sterility Guidance
Inaccurate Measurement	Performance Testing Requirements

III. Special Controls

The proposed special control for these devices is FDA's ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Draft Guidance for Industry and FDA.'' FDA is announcing the public availability of the draft guidance in a notice published elsewhere in this issue of the **Federal Register** and invites interested persons to comment.

IV. Proposed Dates

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

V. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that these classification actions are of a type that do 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 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 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. Reclassification of these devices from class III will relieve all manufacturers of these devices of the cost of complying with the premarket approval requirements in section 515 of the act. Moreover, compliance with special controls proposed for these devices will not impose significant new costs on affected manufacturers because most of these devices already comply with the proposed special controls. Because reclassification will reduce regulatory costs with respect to these devices, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this rule 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 of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VII. Paperwork Reduction Act of 1995

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

VIII. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this proposed rule by April 15, 2002. Submit two copies of any comments, except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The proposed rule and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 868

Medical 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 21 CFR part 868 be amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

1. The authority citation for 21 CFR part 868 continues to read as follows:

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

2. Section 868.2480 is amended by revising paragraph (b) to read as follows:

§ 868.2480 Cutaneous carbon dioxide ($PcCO_2$) monitor.

* * * * *

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Final Guidance for Industry and FDA.''

3. Section 868.2500 is revised to read as follows:

§ 868.2500 Cutaneous oxygen (PcO_2) monitor.

(a) *Identification.* A cutaneous oxygen (PcO_2) monitor is a noninvasive, heated sensor (e.g., a Clark-type polargraphic electrode) placed on the patient's skin that is intended to monitor relative changes in the cutaneous oxygen tension.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's ''Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide ($PcCO_2$) and Oxygen (PcO_2) Monitors; Guidance for Industry and FDA.''

Dated: January 29, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–3281 Filed 2–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Part 89

[Public Notice 3843]

Foreign Prohibitions on Longshore Work by U.S. Nationals

AGENCY: Department of State.

ACTION: Notice of proposed rulemaking.

SUMMARY: In accordance with the Immigration and Nationality Act of 1952, as amended, the Department of State is issuing a proposed rule updating the list of countries whose laws regulations or practices prohibit crewmembers on U.S. ships from performing longshore work. Ships registered in or owned by nationals of the countries listed are ineligible for the reciprocity exception to the prohibition of longshore work by alien crewmembers in U.S. ports and waters.

DATES: Interested parties are invited to submit comments in triplicate by March 12, 2002.

ADDRESSES: Comments may be submitted to Office of Transportation Policy (EB/TRA/OTP/MA), Room 5828, Department of State, Washington, DC 20852–5816.

FOR FURTHER INFORMATION CONTACT: Stephen M. Miller, Office of Transportation Policy (EB/TRA/OTP/MA), Room 5828, Department of State, Washington DC 20852–5816; (202) 647–4915.

SUPPLEMENTARY INFORMATION: Section 258 of the Immigration and Nationality Act of 1952 (the ''Act''), 8 U.S.C. 1288, as added by the Immigration Act of 1990, Public Law 101–649, and subsequently amended, has the effect that alien crewmen may not perform longshore work in the United States. Longshore work is defined to include ''any activity relating to the loading or unloading of cargo, the operation of cargo-related equipment (whether or not integral to the vessel), and the handling of mooring lines on the dock when the vessel is made fast or let go, in the United States or the coastal waters thereof.'' The Act goes on, however, to define a number of exceptions to the general prohibition on such work.

Section 258(b)(2), entitled the ''Exception for safety and environmental protection,'' excludes from the definition of longshore work under this statute ''the loading or unloading of any cargo for which the Secretary of Transportation has, under the authority contained in chapter 37 of Title 46 (relating to Carriage of Liquid Bulk Dangerous Cargoes), section 311 of the Federal Water Pollution Control Act (33 U.S.C. 1321), section 4106 of the Oil Pollution Act of 1990, or sections 5103(b), 5104, 5106, 5107, or 5110 of Title 49 prescribed regulations which govern—(A) the handling or stowage of such cargo, (B) the manning of vessels and the duties, qualifications, and training of the officers and crew of vessels carrying such cargo, and (C) the reduction or elimination of discharge during ballasting, tank cleaning, handling of such cargo.''

Section 258(c), entitled the ''Prevailing practice exception,'' exempts particular activities of longshore work in and about a local port if there is a collective bargaining agreement covering at least 30 percent of the longshore workers in the area that permits the activities or if there is no such collective bargaining agreement and the employer of the alien crewmen files an appropriate attestation, in a timely fashion, that the performance of the activity by alien crewmen is permitted under the prevailing practice of the particular port. The attestation is required for activities consisting of the use of an automated self-unloading conveyor belt or vacuum-actuated system on a vessel only if the Secretary of Labor finds, based on a preponderance of evidence which may be submitted by any interested party, that the performance of such particular activity by alien crewmen is not permitted under the prevailing practice in the area, is during a strike or lockout in the course of a labor dispute, or is intended or designed to influence an election of a bargaining representative for workers in the local port.

Section 258(d), the ''State of Alaska exception,'' provides detailed conditions under which alien crewmen may be allowed to perform longshore activities in Alaska, including the filing of an attestation with the Secretary of Labor at least 30 days before the performance of the work setting forth facts and evidence to show that the employer will make a bona fide request for U.S. longshore workers who are qualified and available, will employ all such workers made available who are needed, and has informed appropriate labor unions, stevedores, and dock operators of the attestation, and that the use of alien crewmembers is not intended or designed to influence an election of bargaining representatives.

Finally, Section 258(e), entitled the ''Reciprocity exception,'' allows the performance of activities constituting longshore work by alien crewmen aboard vessels flagged and owned in countries where such activities are permitted by crews aboard U.S. ships. The Secretary of State (hereinafter, ''the Secretary'') is directed to compile and annually maintain a list, of longshore work by particular activity, of countries where performance of such a particular activity by crewmembers aboard United States vessels is prohibited by law, regulation, or in practice in the country. The Attorney General will use the list to determine whether to permit an alien crew member to perform an activity constituting longshore work in the United States or its coastal waters, in accordance with the conditions set forth in the Act.

The Department of State (hereinafter, ''the Department'') published such a list as a final rule on December 27, 1991 (56 FR 66970), corrected on January 14, 1992 (57 FR 1384). An updated list was initially published on December 13, 1993 (57 FR 65118), and was last published on June 13, 1996 (61 FR 29941).