is safe and effective for its intended uses or is safe for use.) The draft guidance makes the following two fundamental points:

- First, depending on the CAM therapy or practice, a product used in a CAM therapy or practice may be subject to regulation as a biological product, cosmetic, drug, device, or food (including food additives and dietary supplements) under the act or the PHS Act.
- Second, neither the act nor the PHS Act exempts CAM products from regulation.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the regulation of complementary and alternative medicine products by FDA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: December 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–3259 Filed 2–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0020]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document; Oxygen Pressure Regulators and Oxygen Conserving Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA staff entitled ''Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices.'' The draft guidance document is intended to assist manufacturers in complying with minimum performance, testing, and labeling recommendations that are being proposed for these devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to reclassify pressure regulators for use with medical oxygen into class II, subject to special controls. The proposal would also establish separate identification classifications for both oxygen pressure regulators and oxygen conserving devices, and would make those oxygen conserving devices that incorporate a built-in oxygen pressure regulator subject to special controls. This draft guidance is not final nor is it in effect at this time.

DATES: Submit written or electronic comments on the draft guidance by May 29, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 1–800–638–2041. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 101, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Christy Foreman, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0120.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance provides FDA's recommendations to manufacturers for labeling and for determining ignition sensitivity and fault tolerance for oxygen pressure regulators. These devices are intended to convert medical oxygen pressure from a high variable pressure to a lower, more constant working pressure. The device is affixed to a pressurized container of oxygen and the regulator controls the gas flow. These devices are currently regulated as class I devices. However, FDA has received reports of fires and explosions associated with the use of oxygen pressure regulators resulting in serious injury to a number of equipment operators, including one fatality. The draft guidance, if finalized, would serve as the special control for these devices. FDA believes that conformance with the draft special controls guidance, when combined with the general controls of the Federal Food, Drug, and Cosmetic Act (the act), would address the risks associated with oxygen pressure regulators and provide reasonable assurance of their safety and effectiveness.

The draft guidance would also serve as a special control for oxygen conserving devices with a built-in oxygen pressure regulator; a device type already classified into class II under the generic device type noncontinuous ventilator (21 CFR 868.5905). FDA believes that conformance with the draft special controls guidance, when combined with the general controls of the act, will provide reasonable assurance of the safety and effectiveness of oxygen conserving devices with a built-in oxygen pressure regulator.

In the **Federal Register** of May 27, 2003 (68 FR 30214), FDA announced its intention to reclassify oxygen pressure regulators in its semi-annual regulatory agenda. FDA received one comment supporting the establishment of a proposed rule to reclassify these devices.

II. Significance of the Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on oxygen pressure regulators and oxygen conserving devices with a built-in oxygen pressure regulator. It does not create or confer any rights for or on any person and would not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Class II Special Controls Guidance Document: Pressure Regulators For Use With Medical Oxygen and Oxygen Conserving Devices,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document, or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1227 to identify the guidance you are requesting.

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 Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E (premarket notification procedures) have been approved under OMB Control number 0910–0120. The labeling statements that would be required by this regulation are ''public disclosure[s] of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public * * *'' (5 CFR 1320.3(c)(2)). Accordingly, FDA concludes that the labeling requirements in this proposed rule are not subject to review by OMB under the PRA.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 8, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–3254 Filed 2–26–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to Office of Management and Budget under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The Nurse Faculty Loan Program (NFLP): Annual Operating Report (AOR) Form—NEW

Under Title VIII of the Public Health Service Act, as amended by Public Law 107–205, Section 846A, the Secretary of Health and Human Services (HHS) enters into an agreement with a school of nursing to establish and operate the NFLP fund. HHS makes an award to the school in the form of a Federal Capital Contribution (FCC). The award is used to establish a distinct account for the NFLP loan fund at the school or is deposited into an existing NFLP fund. The school of nursing makes loans from the NFLP fund to eligible students enrolled full-time in a master's or doctoral nursing education program that will prepare them to become qualified nursing faculty. Following graduation from the NFLP lending school, loan recipients may receive up to 85 percent NFLP loan cancellation over a consecutive four-year period in exchange for service as full-time faculty at a school of nursing. The NFLP lending school collects any portion of the loan that is not cancelled and any loan in repayment and deposits these monies into the NFLP loan fund to make additional NFLP loans. The school of nursing must keep records of all NFLP loan fund transactions.

The NFLP Annual Operating Report will be used to collect information relating to the NFLP loan fund operations and financial activities for a specified reporting period (July 1 through June 30 of the academic year). Participating schools will complete and submit the AOR annually to provide the Federal Government with current and cumulative information on: (1) The number and amount of loans made, (2) the number of NFLP recipients and graduates, (3) the number and amount of loans collected, (4) the number and amount of loans in repayment, (5) the number of NFLP graduates employed as nurse faculty, (6) NFLP loan fund receipts, disbursements and other related cost. The NFLP loan fund balance is used to determine future awards to the school.