collection of information to OMB for review and clearance.

Exemptions and Variances from the Performance Standard for Electrode Lead Wires and Patient Cables

FDA regulations in part 898 (21 CFR part 898) mandate a performance standard for electrode lead wires and patient cables. The purpose of the performance standard is to prevent electrocution from the use of unprotected electrode lead wires and patient cables with medical devices. To provide maximum flexibility in situations where the electrical accidents can be prevented in other ways, § 898.14 provides that any person subject to the performance standard may submit a petition under 21 CFR 10.30 requesting an exemption or variance from the standard. The petition must demonstrate why compliance with the standard is unnecessary or unfeasible and what alternate means will be used to protect the public health. FDA will use this information to determine whether granting an exemption is in the best interests of the public health. Allowing for exemptions and variances will provide for flexibility while assuring public health protection. Section 898.14 is stayed pending OMB clearance. FDA will announce the effective date of § 898.14 in the **Federal Register**. Anticipated respondents to this collection of information are medical device manufacturers and distributors, and health care facilities.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	50	1	50	10	500

[1] There are no capital costs or operating maintenance costs associated with this collection of information.

Dated: January 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1294 Filed 1–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0015]

Medical Devices; Exemptions From Premarket Notification; Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of class II (special controls) devices, subject to certain limitations, that are now exempt from the premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (the FDAMA). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet a requirement of the FDAMA.

DATES: Effective January 21, 1998. Comments on this notice should be submitted within 90 days of publication. The agency will review any comments submitted within the 90-day comment period and will consider whether the list of class II devices that are exempt from the premarket notification requirements should be modified.

ADDRESSES: Submit written comments on this notice to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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 (Pub. L. 94–295)), as amended by the the Safe Medical Devices Act of 1990 (the SMDA (Pub. L. 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 which 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 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. Unless exempted from premarket notification requirements, persons may not market a new device, under section 510(k), unless they receive a substantial equivalence order from FDA or an order reclassifying the device into class I or class II (section 513(I) of the act).

On November 21, 1997, the President signed into law the FDAMA. Section

206 of the 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 the 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 (generally referred to as a premarket notification or ''510(k)'') 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**.

Section 510(m)(2) of the act provides that, 1 day after date of publication of the list under section 510(m)(1), 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. 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

In considering whether to exempt class II devices from premarket notification, FDA focused on whether premarket notification for the type of device is necessary to provide reasonable assurance of safety and effectiveness of the device. FDA considered the following factors: (1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials (when making these determinations, FDA has considered the risks associated with false or misleading claims, and the frequency, persistence, cause or seriousness of the inherent risks of the device); (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either: (a) Be readily detectable by users by visual examination or other means such as routine testing, before causing harm, e.g., testing of a clinical laboratory reagent with positive and negative controls; or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification.

FDA also considered that even when exempting devices, these devices would still be subject to the limitations on exemptions, as described in section III of this document.

III. Limitations on Exemptions

The exemption from the requirement of premarket notification for a generic type of device listed in this document applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. Accordingly, a class II device listed in this document is not exempt if such device: (1) Has an intended use that is different from the intended use of a legally marketed device in that generic type; e.g., the device is intended for a different medical purpose, or the device is intended for lay use instead of use by health care professionals; or (2) operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization or amplification technology rather than culture or immunoassay technology; or (3) is an in-vitro device: That is intended for use in the diagnosis, monitoring or screening of neoplastic diseases with the exception of immunohistochemical devices; is intended for use in screening or diagnosis of familial and acquired genetic disorders, including inborn errors of metabolism; is intended for measuring an analyte which serves as a surrogate marker for screening, diagnosis, or monitoring life threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction, or to monitor therapy; is intended to assess the risk of cardiovascular diseases; is intended for use in diabetes management; is intended to identify or infer the identity of a microorganism directly from clinical material; is intended for detection of antibodies to microorganisms other than immunoglobulin G (IgG) and IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma; uses noninvasive testing; is intended for near-patient testing (point of care).

Class II devices incorporating such changes or modifications are not exempt from premarket notification because FDA has determined that premarket notification is necessary to assure the safety and effectiveness of the device.

In addition to the general limitation on exemptions that applies to all class II devices that are described previously, FDA may limit the exemption from premarket notification requirements to certain devices within a generic class. For example, FDA, in section IV of this document, is listing the exemption of the biofeedback device, but limits the exemption to prescription battery powered devices that are indicated for relaxation training and muscle reeducation. All other biofeedback devices are still subject to premarket notification requirements because FDA determined that premarket notification was necessary to provide a reasonable assurance of safety and effectiveness for these devices.

FDA advises, additionally, that an exemption from the requirement of premarket notification does not mean that the device is exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation. Indeed, FDA's determination that premarket notification was unnecessary to provide a reasonable assurance of safety and effectiveness for devices listed in this document is based, in part, on the assurance of safety and effectiveness that other regulatory controls, such as current good manufacturing practice requirements, provide.

Persons with pending 510(k) submissions for devices that are exempted in this document, subject to the limitations on exemptions, should withdraw their submissions.

IV. List of Class II Devices Exempted

FDA is identifying the following devices as class II devices that, as of the date of publication of this document, are exempt from the requirement to submit a premarket notification under section 510(k) of the act, subject to limitations on exemptions in this document:

TABLE 1.—EXEMPTED CLASS II DEVICES

21 CFR Sections	Name of Devices
862.1440	Lactate dehydrogenase test system
862.1635	Total protein test system
864.6100	Bleeding time device
864.6400	Hematocrit measuring device
864.9160	Blood group substances of nonhuman origin for in vitro diagnostic use
864.9550	Lectins and protectins
864.9575	Environmental chamber for storage of platelet concentrate
864.9600	Potentiating media for in vitro diagnostic use
864.9700	Blood storage refrigerator and blood storage freezer
866.3060	Blastomyces dermatitidis serological reagents
866.3085	Brucella spp. serological reagents
866.3135	Coccidioides immitis serological reagents
866.3165	Cryptococcus neoformans serological reagents
866.3220	Entamoeba histolytica serological reagents
866.3280	Francisella tularensis serological reagents
866.3300	Haemophilus spp. serological reagents
866.3320	Histoplasma capsulatum serological reagents
866.3350	Leptospira spp. serological reagents
866.3415	Pseudomonas spp. serological reagents
866.3460	Rabiesvirus immunofluorescent reagents
866.3550	Salmonella spp. serological reagents
866.3660	Shigella spp. serological reagents
866.3930	Vibrio cholerae serological reagents
866.5040	Albumin immunological test system
866.5210	Ceruloplasmin immunological test system
866.5320	Properdin factor B immunological test system
866.5380	Free secretory component immunological test system
866.5460	Haptoglobin immunological test system
866.5470	Hemoglobin immunological test system
866.5490	Hemopexin immunological test system
876.1620	Urodynamics measurement system
876.1800	Urinev flow or volume measuring system
876.2040	Enuresis alarm
876.4370	Gastroenterlogy-urology evacuator
876.4650	Water jet renal stone dislodger system
876.4680	Uretal stone dislodger
876.4890(b)(1)	Urological table and accessories
876.5250(b)(1)	Urine collector and accessories
880.2200	Liquid crystal forehead temperature strip
880.2920	Clinical mercury thermometer
880.5100	AC-powered adjustable hospital bed
880.5140	Pediatric hospital bed
880.5475	Jet lavage
880.5500	AC-powered patient lift
880.5550	Alternating pressure air flotation mattress
880.6740	Vacuum-powered body fluid suction apparatus
880.6775	Powered patient transfer device
880.6910	Wheeled stretcher
882.5050	Biofeedback device[1]
886.3100	Ophthalmic tantalum clip
886.3130	Ophthalmic conformer
886.3800	Scleral shell
890.1925	Isokinetic testing and evaluation system
890.3500	External assembled lower limb prosthesis
890.3710	Powered communication system
890.3725	Powered environmental control system
890.5160	Air-fluidized bed
890.5170	Powered flotation therapy bed
890.5225	Powered patient rotation bed
890.5720	Water circulating hot or cold pack
890.5740	Powered heating pad
892.1980	Radiologic table

[1] Exemption is limited to prescription battery powered devices that are indicated for relaxation training and muscle reeducation and prescription use.

V. Additional Exemptions

Under section 510(m)(2) of the act, as described previously, interested persons may request that FDA exempt any class II device from the premarket notification requirements. The request should identify the generic type of device by the CFR section number (e.g., 21 CFR 884.1234) and state clearly why the submitter believes the factors described in section II of this document apply, and that premarket notification requirements

are not necessary to provide reasonable assurance of the safety and effectiveness of the device. By February 19, 1998, FDA will provide guidance on how to request such an exemption.

Dated: January 15, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–1485 Filed 1–16–98; 12:00 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Immunology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Immunology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on February 2, 1998, 9:30 a.m. to 6:30 p.m.

Location: Parklawn Bldg., conference rooms D & E, 5600 Fishers Lane, Rockville, MD.

Contact Person: Peter E. Maxim, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12516. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss proposed prescription home use labeling for a unitized bladder cancer tumor marker assay used to aid in the detection of bladder cancer recurrence. Also, the committee will discuss, make recommendations, and vote on a premarket approval application for a free PSA (prostate-specific antigen) assay. The assay is intended to be used in men over the age of 50 with a negative digital rectal examination and a total serum PSA measurement of 4.0 to 10.0 nanograms/milliliter. The free PSA/total PSA ratio aids in the differentiation between benign and malignant prostate disease.

Procedure: On February 2, 1998, from 10 a.m. to 6:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by January 29, 1998. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before January 29, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On February 2, 1998, from 9:30 a.m. to 10 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). FDA staff will present to the committee confidential information regarding present or future issues.

FDA regrets that it was unable to publish this notice 15 days prior to the February 2, 1998, Immunology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring this issue to public discussion and qualified members of the Immunology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 15, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–1418 Filed 1–15–98; 3:51 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0007]

Draft ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products or Animal Plasma or Serum-Derived Products;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products or Animal Plasma or Serum-Derived Products.'' The draft guidance document is intended to assist applicants in the preparation of the content and format of the chemistry, manufacturing, and controls (CMC) section and the establishment description section of a biologics license application (BLA), revised Form FDA 356h for human plasma-derived biological products, animal plasma, or serum-derived products. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and FDA Modernization Act of 1997, and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time, however, comments should be submitted by April 21, 1998, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Plasma-Derived Biological Products or Animal Plasma or Serum-Derived Products'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests.