individual's compensation under the plan.

5. A list showing the number and a brief identification of each material foreign patent for an invention not covered by a United States patent, but only if we request you to file the list.

6. A statement explaining in reasonable detail how earnings per share information was calculated, unless the computation is clear from material contained in the registration statement or report.

7. A statement explaining in reasonable detail how any ratio of earning to fixed charges, any ratio of earnings to combined fixed charges and preferred stock dividends or any other ratios in the registration statement or report were calculated.

8. A list of all your subsidiaries, their jurisdiction of incorporation and the names under which they do business. You may omit the names of subsidiaries that, in the aggregate, would not be a ''significant subsidiary'' as defined in rule 1–02(w) of Regulation S–X as of the end of the year covered by the report. You may omit the names of multiple wholly owned subsidiaries carrying on the same line of business, such as chain stores or service stations, if you give the name of the immediate parent company, the line of business and the number of omitted subsidiaries broken down by U.S. and foreign operations.

9. Statement pursuant to the instructions to Item 8.A.4, regarding the financial statements filed in registration statements for initial public offerings of securities.

10. (a) Any additional exhibits you wish to file as part of the registration statement or report, clearly marked to indicate their subject matter, and (b) any document or part of a document incorporated by reference in this filing if it is not otherwise required to be filed or is not a Commission filed document incorporated in a Securities Act registration statement.

* * * * *

PART 260—GENERAL RULES AND REGULATIONS, TRUST INDENTURE ACT OF 1939

50. The authority citation for part 260 continues to read as follows:

Authority: 15 U.S.C. 77eee, 77ggg, 77nnn, 78sss, 78*ll*(d), 80b–3, 80b–4, and 80b–11.

51. Amend § 260.0–11 by removing in paragraph (b)(2) the words ''Item 9 of Form 20–F (§ 249.220f of this chapter), management's discussion and analysis of financial condition and results of operations,'' and adding, in their place, the words ''Item 5 of Form 20–F (§ 249.220f of this chapter), 'Operating and Financial Review and Prospects,' ''; and by removing in paragraph (c)(3) the words ''Item 9 of Form 20–F'' and adding, in their place, the words ''Item 5 of Form 20–F''.

Dated: February 2, 1999.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

Appendix A

Note: This Appendix A to the preamble will not appear in the Code of Federal Regulations.

Securities and Exchange Commission

Regulatory Flexibility Act Certification

I, Arthur Levitt, Chairman of the Securities and Exchange Commission, hereby certify pursuant to 5 U.S.C. 605(b) that the following amendments to the Commission's rules and forms would not, if adopted, have a significant economic impact on a substantial number of small entities in the United States: changes to Forms F–1, F–2, F–3, F–4, F–6 and S–11 and Rules 175, 405, 434 and 463 under the Securities Act; changes to Form 20–F and Rules 3b–4, 3b–6, 13a–10 and 15d–10 under the Exchange Act; changes to Items 402, 512 and 601 of Regulation S–K; changes to Rules 3–01, 3–02, 3–12, 3–19 and 3–20 of Regulation S–X; changes to Item 310 of Regulation S–B; and changes to Rule 0–11 under the Trust Indenture Act. The reasons for this certification are as follows:

The amendments are unlikely to have a significant economic impact because they are based on current law and practice. Moreover, the amendments are intended primarily to facilitate offerings and listings of securities by foreign private issuers, by conforming the disclosure requirements of Form 20–F more closely to international disclosure norms. The resulting incremental reduction in the expense, time and effort of making offerings in multiple jurisdictions will directly affect only foreign entities that issue securities, rather than U.S. entities.

One possible indirect result of adopting the amendments is that foreign companies may offer securities to U.S. small entity investors who previously would have been excluded due to the time and expense of compliance with the regulatory requirements of more than one jurisdiction. The potential increase in foreign offerings in the United States may have some indirect impact on U.S. small entity offerings. However, the indirect impact is likely to be small, and its effect is not expected to be significant for a substantial number of small entities in the United States.

The proposed amendments would not have a significant economic impact on a substantial number of small entities. The primary effect of the proposals would be on foreign entities, which we believe are not considered as small entities under the Regulatory Flexibility Act.

Dated: February 2, 1999.

Arthur Levitt,

Chairman.

[FR Doc. 99–2931 Filed 2–8–99; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1020

[Docket No. 98N–1170]

Medical Devices; Sunlamp Products Performance Standard; Request for Comments and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intent to propose amendments to the performance standard for sunlamp products. The agency is taking this action to address concerns about the adequacy of the warnings on sunlamp products, current recommended exposure schedule to minimize risk to customers who choose to produce and maintain a tan, current labeling for replacement lamps, and current health warnings which do not reflect recent advances in photobiological research. FDA is soliciting comments and information from interested persons concerning the subject matter of the proposed amendments.

DATES: Written comments by May 10, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Individuals or organizations wishing to receive copies of draft amendments or related documents distributed for review during the development of these amendments may have their names placed on a mailing list by writing to Office of Science and Technology (HFZ–114), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, FAX 301–594–6775, e-mail address HWC@CDRH.FDA.GOV.

FOR FURTHER INFORMATION CONTACT: W. Howard Cyr, Center for Devices and Radiological Health (HFZ–114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–7179.

SUPPLEMENTARY INFORMATION:

I. Background

The Safe Medical Devices Act of 1990 (Pub. L. 101–629), enacted on November 28, 1990, transferred the provisions of the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90–602) from Title III of the Public Health Service Act to Chapter V, subchapter C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360hh *et seq.*). This authority provides for developing, amending, and administering radiation safety performance standards for electronic products.

Sunlamp products are class I medical devices exempt from premarket notification requirements (21 CFR 878.4635). These products are intended to provide ultraviolet (UV) radiation to tan the skin. As class I devices, sunlamp products are subject to general controls such as registration, listing, and current good manufacturing practices. Sunlamp products are also subject to the regulations for electronic product radiation control including parts 1000 through 1010 and § 1040.20 (21 CFR parts 1000 through 1010 and 21 CFR 1040.20).

The sunlamp performance standard in § 1040.20 was originally published in the **Federal Register** of November 9, 1979 (44 FR 65352). On September 6, 1985 (50 FR 36548), FDA amended § 1040.20 and made it applicable to all sunlamp products manufactured on or after September 8, 1986. On August 21, 1986, FDA issued a guidance entitled ''Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products.'' The guidance explained the criteria FDA uses to evaluate the adequacy of the exposure schedule and the recommended maximum exposure time for sunlamp products. On September 2, 1986, FDA issued another guidance entitled ''Policy on Lamp Compatibility.'' The guidance listed the criteria FDA uses to evaluate lamp compatibility for sunlamp products.

Before proposing any electronic product performance standards, FDA is required to consult a statutory advisory committee, the Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC) (21 U.S.C. 360kk(f)(1)(A)). At the September 23 and 24, 1998, meeting of TEPRSSC, FDA presented general concepts for amendments to the performance standard for sunlamp products. The committee recommended that FDA pursue development of the amendments. FDA intends to present more specific proposals to amend the performance standard to TEPRSSC prior to the publication of a proposed rule in the **Federal Register**.

FDA is concerned that inadequate attention is being paid to the recommended exposure schedule which should be designed to minimize risks for those who choose to produce and maintain a tan. FDA is further concerned that the warnings for sunlamp products are not reaching many users of sunlamp products and that the existing exposure schedule does not take into account the variations in individual human UV sensitivity. In order to update the current sunlamp product standards, FDA is considering revising § 1040.20.

In addition, sunlamp technology continues to change. These changes can affect both the intensity and the spectral characteristics of the UV from sunlamps. Because there is no uniform grading/rating system, choosing a replacement lamp can be confusing for tanning bed owners. Owners choosing replacement lamps must consider lamp compatibility as well as compliance with FDA's performance standard in order to protect users from excessive exposure to UV.

In addition to concerns about the warnings, labeling, and exposure schedule, FDA is aware of new research findings that suggest a stronger association between exposures to ultraviolet radiation and the increased incidence of skin cancer that has been observed in the U.S. population. Some of this increase has been linked to intense, intermittent exposures to solar radiation, but other research suggests that chronic, less intense exposures to ultraviolet radiation also contribute to skin cancer. Research has identified the fundamental chemical damage that occurs in the genetic material of humans and has linked some skin cancers to changes in specific genes. These scientific findings have led many in the medical community to strongly suggest that consumers avoid intense, intermittent exposures (the type that could produce sunburns) to ultraviolet radiation, and also minimize other UV exposures as well.

There are other deleterious effects from human exposure to UV radiation. They include blistering burns, skin erythema, photoaging, and photoallergic/photosensitive drug interactions. UV radiation may induce damage in the cornea, lens, and retina of the eye, which in extreme cases leads to permanent loss of vision. UV exposure is immunosuppressive, and can have an impact on the development of many diseases.

Some research has linked skin cancer to exposures to sunlamp products, and some research has even suggested an association between the use of sunlamps and malignant melanoma. This association is not definitive. FDA solicits comments and information as to whether a warning about possible melanoma induction should be part of sunlamp labels. To provide users with sufficient information for the safe use of these devices at tanning salons and for home sunlamp products, FDA seeks comments and information on suggested changes to the current sunlamp labels.

After considering the risks, some consumers may still choose to tan, either by exposure to the sun or by use of sunlamp products. Those consumers who use sunlamp products should obtain their tan with the least amount of risk from sunburn and eye damage. Therefore, FDA seeks advice on a recommended exposure schedule which would minimize the risks of adverse effects while still producing and maintaining a tan.

II. Revisions Under Consideration

FDA believes that amendment of the current performance standard is necessary to keep pace with changes in technology and advances in research related to the use of sunlamp products. The following discussion is intended to describe the need for the revision and FDA's proposed approach. Comments received from this advance notice of proposed rulemaking (ANPRM) will be used to develop any proposed amendments. Any proposed regulatory changes or standards amendments will be included in a future proposed rule. FDA is soliciting comments on all aspects of this ANPRM, and specifically requests comments on the following proposed amendments:

1. FDA is considering revising and updating the current sunlamp product performance standard (§ 1040.20) and harmonizing it with the International Electrotechnical Committee Standard 335–2–27 for UV and infrared emitting appliances. After consulting with international standards organizations and evaluation of the current scientific knowledge, FDA intends to develop a recommended exposure schedule which will become part of the directions for use of the sunlamp product. As part of the development process, FDA intends to review the material on effects of UVA and UVB on skin, the effects of UV exposure on melanoma induction, and the use of photobiological action spectra as a basis for risk assessment in health protection and product safety discussed at the American Society for Photobiology and European Society for Photobiology Joint Workshop on UV and Melanoma, Snowbird, Utah, July 11

through 15, 1998; the International Symposium and Workshop on Measurements of Optical Radiation Hazards, at the National Institute for Standards and Technology, Gaithersburg, MD, September 1 through 3, 1998; and (3) the Research Workshop on Risks and Benefits of Exposure to Ultraviolet Radiation and Tanning, at the National Institutes of Health, Bethesda, MD, September 16 through 18, 1998. The proceedings of these meetings describe current research findings that show a stronger correlation between UV exposure and skin cancer, photoaging, and photoimmunological effects.

2. FDA is considering revising and updating its August 21, 1986, guidance on the determination of the maximum timer interval and recommended exposure schedule for sunlamp products entitled, ''Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products.'' FDA is concerned that inadequate attention is being paid to current recommended exposure schedules and that current guidance may allow higher exposures than are necessary to produce and maintain a tan, and it does not incorporate the differences in individual human sensitivity to UV exposure. FDA intends to update this guidance after reviewing and evaluating material presented at the meetings listed previously and other available information. FDA is further considering incorporating the previous guidance into the sunlamp product performance standard because it believes such incorporation would result in a more comprehensive regulatory standard with all relevant information for compliance in the standard.

3. FDA is considering adding a provision clarifying that manufacturing includes the modification of a sunlamp product, previously certified under § 1010.2, by any person engaged in the business of manufacturing, assembling or modifying sunlamp products if the modification affects any aspect of the product's performance, information or intended function for which § 1040.20 has an applicable requirement. This addition would clarify that sunlamp products are being regulated like other products regulated under § 1010.2. FDA is also considering requiring the manufacturer who performs such modification to recertify and re-identify the product in accordance with the provisions of §§ 1010.2 and 1010.3. This potential amendment is intended to clarify the responsibilities of firms and individuals who are in the business of installing ultraviolet lamps and new timers with different performance characteristics than the original lamps and timers in previously certified products.

4. FDA is concerned that the current warning label is not read by many tanning salon patrons because it is too long and detailed. Therefore, FDA is considering updating the warning statement required by § 1040.20(d)(1)(i) to simplify the wording and to highlight the risk of skin cancers. In order to update the warning statements, FDA intends to review and evaluate epidemiological and mechanistic information on UV exposure-related skin cancers, including possibly fatal cutaneous malignant melanoma. In developing its specific proposal for this item, FDA will be reviewing the material presented at the meetings cited previously and other available information.

5. FDA is considering requiring the reproduction of the text of the warning statement specified in § 1040.20(d)(1)(i) in catalogs, specification sheets, and brochures pertaining to sunlamp products. FDA is concerned that consumers who purchase sunlamp products through catalog mail order or through catalogs on electronic media may not receive information about the associated hazards and risks until the products are delivered to their homes and unpacked.

6. To simplify appropriate lamp replacement, FDA is considering the development of a biological efficacy rating scale for ultraviolet lamps intended for use in sunlamp products. Lamp technology continues to evolve, affecting the levels of UV exposure, the spectral characteristics and, therefore, the biological efficacy of ultraviolet lamp radiation. At present, a label that specifies the type of lamps suitable for replacement in the product is required on sunlamp products and in the user instructions. As new lamps and new lamp manufacturers enter the marketplace, while other manufacturers abandon the marketplace, it is increasingly cumbersome to keep track of individual lamp designations which are compatible with the product and compliant with the standard. In order to simplify the process, especially for industry and State regulators, FDA is considering a uniform grading/rating system.

III. Comments

Interested persons may, on or before May 10, 1999, submit to the Dockets Management Branch (address above) written comments regarding this ANPRM. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday. This ANPRM is issued under section 531 *et seq.* of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360hh *et seq.*) and under authority of the Commissioner of Food and Drugs.

Dated: February 2, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–3109 Filed 2–8–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD07–98–048]

RIN 2115–AE47

Drawbridge Regulations: Grand Canal, FL

AGENCY: Coast Guard, DOT.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the regulation governing the operation of the Tortoise Island drawbridge across the Grand Canal at Tortoise Island, Brevard County, Florida. The Coast Guard has reconsidered its original proposal in the NPRM published on August 28, 1998, extending the 2 hours advance notice for opening on signal to include Friday and Saturday nights and evenings preceding federal holidays, and now is proposing only 30 minutes advance notice for opening the bridge on Friday and Saturday nights and evenings preceding federal holidays. This rule is intended to reduce the requirement to maintain bridgetender service on the bridge during evening hours while still meeting the reasonable needs of navigation on Grand Canal.

DATES: Comments must be received on or before April 12, 1999.

ADDRESSES: Comments may be mailed to Commander (oan) Seventh Coast Guard District, 909 SE 1st Avenue, Miami, Florida 33131–3050, or may be delivered to room 406 at the above address between 7:30 a.m. and 4:00 p.m. Monday through Friday, except federal holidays. The telephone number is (305) 536–6546. The Commander, Seventh Coast Guard District, maintains the