Modification, OPT10 9205–57, Wing Rear Attachment Bracket, dated April 1996; and

(ii) Incorporate wing rear attachment fitting reinforcement kit No. OPT10 920300 in accordance with the Technical Instruction of Modification, OPT109203–57, Wing Rear Attachment Bracket, dated April 1996.

(3) If any fitting is not found cracked, prior to further flight, incorporate wing rear attachment fitting reinforcement kit No. OPT10 920300 in accordance with the Technical Instruction of Modification, OPT109203–57, Wing Rear Attachment Bracket, dated April 1996.

(b) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(c) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Small Airplane Directorate, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(d) All persons affected by this directive may obtain copies of the documents referred to herein upon request to Socata—Groupe Aerospatiale, Socata Product Support, Aeroport Tarbes-Ossun-Lourdes, B P 930, 65009 Tarbes Cedex, France; or Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023. These documents may also be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Note 5: The subject of this AD is addressed in French AD 94–249(A)R1, dated June 19, 1996.

Issued in Kansas City, Missouri, on December 10, 1997.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–32727 Filed 12–15–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 97N–0481]

Gastroenterology-Urology Devices: Reclassification of the Penile Rigidity Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the penile rigidity implant, a medical device intended to provide penile rigidity in men diagnosed as having erectile dysfunction, from class III to class II. The special controls identified in this proposed rule are the physician and patient labeling, biocompatibility testing, mechanical reliability performance testing, clinical testing, and sterilization requirements described in FDA's guidance document entitled ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants.'' This reclassification is being proposed on the agency's own initiative based on new information. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA).

DATES: Written comments by March 16, 1998. FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

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

FOR FURTHER INFORMATION CONTACT: John H. Baxley, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The act, as amended by the 1976 amendments (Pub. L. 94–295) and the SMDA (Pub. L. 101–629), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as post amendment devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval. Section 515(b) of the act describes a two step regulatory process. A notice of proposed rulemaking in the Federal Register, which includes the proposed regulation, proposed findings of risks and benefits of the device, an opportunity for the submission of comments and an opportunity to request reclassification, is followed by the final rule which issues the regulation.

In 1990, the SMDA added section 515(i) to the act. This section requires FDA to issue an order to manufacturers of preamendment class III devices for which no final regulation requiring the submission of PMA's has been issued to submit to the agency a summary of, and a citation to any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information which has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 519 of the act requires manufacturers, importers, distributors and device user facilities to submit adverse event reports of certain device-related events. Section 515(i) of the act also directs FDA to either revise the classification of the device into class I or class II or require the device to remain in class III and establish a schedule for the issuance of a rule requiring the submission of PMA's for those devices remaining in class III.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA announced its strategy and made available a document setting forth its strategy for implementing the provisions of the SMDA that require FDA to review the classification of preamendment class III devices. In accordance to this plan, the agency divided preamendment class III devices into the following three groups: Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness, but are no longer used or are in very limited use. Group 2 devices are devices that FDA believes have a high potential for being reclassified into class II. Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. FDA also announced its intent to call for submission of PMA's for the 15 highest priority devices in Group 3, and for all Group 1 devices. The agency also announced its intent to issue an order under section 515(i) of the act for the remaining Group 3 devices and for all of the Group 2 devices.

In the **Federal Register** of August 14, 1995 (60 FR 41984), 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. Each of the orders described in detail the format for submitting the type of information required by section 515(i) of the act so that the information submitted would clearly support reclassification or indicate that a device should be retained in class III. The orders also scheduled the required submissions in groups of nine devices at 6-month intervals beginning with August 14, 1996. The device proposed in this regulation for reclassification was included in the August 14, 1995, order on Group 2 devices (Docket No. 94N–0417).

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) However, regardless of whether data before the agency are past or new data, the ''new information'' on which any reclassification is based is required to consist of ''valid scientific evidence'' as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of PMA's. (See section 520(c) of the act (21 U.S.C. 360j(c)).)

II. Regulatory History of the Device

In the **Federal Register** of November 23, 1983 (48 FR 53012 at 53023), FDA issued a final rule classifying the penile rigidity implant into class III (21 CFR 876.3630). The preamble to the proposal to classify the device (46 FR 7578, January 23, 1981) included the recommendations of the Gastroenterology and Urology Devices Advisory Panel and the General and Plastic Surgery Devices Advisory Panel (the Panels), FDA advisory committees, which met regarding the classification of the device. The Panels both recommended that the device be classified in class II, listing poor tissue compatibility, tissue trauma, and device structural problems as potential risks of the device and citing that general controls and performance standards would provide reasonable assurance of the safety and effectiveness of the device.

FDA disagreed with the Panels' recommendations and proposed that the penile rigidity implant be classified into class III. The proposal stated that the agency believed that insufficient information existed to determine that general controls would provide reasonable assurance of safety and effectiveness of the device, or to establish a performance standard to provide this assurance. The proposal stated that premarket approval is necessary for this device because it presents a potential unreasonable risk of injury due to: (1) Adverse tissue reaction if the materials used in the construction of the device are not biocompatible; (2) infection resulting from defects in the design, construction, packaging, or processing of the device; (3) urinary retention if the prosthesis compresses the urethra; and (4) erosion or malfunction if the implant is improperly sized or mechanically breaks. In support of its proposal to strengthen regulatory surveillance of the device, FDA cited references supporting the proposed classification.

In the **Federal Register** of April 7, 1981 (46 FR 20687), FDA reopened the comment period for the proposed regulation classifying this device for an additional 60 days. This addition 60-day comment period was established because the proposed classification regulation for the penile rigidity implant stated incorrectly that the Gastroenterology and Urology Devices Advisory Panel recommended that the device be classified into class III, rather than class II. In the April 7, 1981 notice, FDA announced that on April 13, 1981, a meeting of the Panel would be held. During this meeting, the Panel reviewed all comments, and again recommended that the penile rigidity implant be classified into class II. No other comments were received during the remainder of the comment period. Again, FDA disagreed with the Panel's recommendation and proposed that the penile rigidity implant be classified into class III. FDA searched the published literature and further documented the potential risks to health resulting from silicone implants, such as silicone particle migration and allergic or adverse tissue reaction.

The preamble to the November 23, 1983 (48 FR 53012), final rule classifying the device into class III advised that the earliest date by which PMA's for the device could be required was June 30, 1986, or 90 days after issuance of a rule requiring premarket approval for the device, whichever occurs later.

In the **Federal Register** of May 6, 1994, FDA categorized the penile rigidity implant as a Group 2 device, which FDA believes has a high potential for being reclassified into class II. The agency also announced its intent to issue an order under section 515(i) of the act for Group 2 devices.

In the **Federal Register** of August 14, 1995 (60 FR 41984 at 41986), FDA published an order requiring manufacturers of penile rigidity implants to submit safety and effectiveness information in accordance with the Preamendments Class III Strategy for implementing section 515(i) of the act. On August 14, 1996, two

summaries of safety and effectiveness information were submitted to the agency (Refs. 39 and 40). These summaries recommended that the penile rigidity implant be reclassified into class II and provide information to assist FDA in reclassifying this device.

In accordance with sections 513(e) of the act and 21 CFR 860.130, based on new information with respect to the device, FDA, on its own initiative, is proposing to reclassify this device from class III to class II when intended to provide penile rigidity in men diagnosed as having erectile dysfunction.

Consistent with the act and the regulation, FDA did not refer, because of the reasons stated herein, the proposed reclassification to the Panel for its recommendation on the requested change in classification.

III. Device Description

A penile rigidity implant is a device that consists of a pair of semi-rigid rods implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction.

The proposed rule to reclassify the penile rigidity implant applies to legally marketed penile rigidity implants identified above that were commercially distributed before May 28, 1976, and to devices introduced into commercial distribution since that date that have been found to be substantially equivalent to such penile rigidity implants.

IV. Proposed Reclassification

FDA is proposing that the penile rigidity implant be reclassified from class III to class II. FDA believes that class II with special controls (specifically, the physician and patient labeling, biocompatibility testing, mechanical reliability performance testing, clinical testing, and sterilization requirements described in FDA's guidance document entitled ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants'') would provide a reasonable assurance of safety and effectiveness.

V. Risks to Health

After considering the information discussed by the Panels during the classification proceedings, as well as the published literature, Medical Device Reports, and 515(i) submissions of safety and effectiveness information, FDA has evaluated the risks associated with the penile rigidity implant. FDA now believes that the following are risks associated with the use of the penile rigidity implant:

A. Infection

Infection is a risk common to all surgical procedures and implants. For penile rigidity implants, infection is typically reported to occur in 1 to 8 percent of cases (average of 3 percent) (Refs. 3, 5, 7, 9, 13, 23, and 26). In most cases, these infections result from seeding at the time of surgery and are reported as early post-operative complications (Refs. 5 and 23). However, late occurring prosthetic infections have been noted, and they are believed to be hematogenous in nature as the result of dental or other surgical procedures (Refs. 5, 6, 13, 17, and 23).

The best defense against infections is prophylaxis, particularly the selection of patients who are free of infection, the administration of an intraoperative shave and scrub, the use of perioperative antibiotics, and adherence to strict surgical technique (Refs. 5, 6, 18, 23, 26, and 32). However, even with these preventive measures, certain patients, such as those with a history of urinary tract infection, are still at risk for penile prosthesis infection (Refs. 5, 23, and 32).

The treatment of an infected penile prosthesis is removal of the device combined with appropriate antibiotic medications (Refs. 21, 23, and 26). A new device can either be placed at the time of removal, or 3 to 12 months later (Refs. 5, 7, 23, and 26). Sequela to penile prosthesis infections include scarring/fibrosis at the site of the prior implant, which could make reimplantation of a penile rigidity implant difficult (Refs. 21 and 30). Serious sequela are rare (Ref. 11).

B. Erosion, Migration, and Extrusion

Erosion refers to the breakdown of tissue adjacent to the device. Migration refers to the movement of the implant within the body. In some cases, erosion may result in the external migration of the device, which is called extrusion. Erosion, migration, and extrusion of a penile rigidity implant are uncommon (<3 percent) complications (Ref. 28). Erosion and/or extrusion usually occur distally through either the urethra or the glans penis (Ref. 26). Proximal migration of the device without erosion or extrusion can result in inadequate support of the glans penis (often called ''floppy glans'' or ''SST deformity'') (Refs. 28 and 31).

Factors contributing to erosion, migration, or extrusion include implantation of a device that is too large, iatrogenic injury to the surrounding tissues (i.e., urethra, corpora, etc.), and infection (Refs. 26, 27, and 28). Additionally, it is possible that malfunction of the implant could lead to erosion, migration, or extrusion if rough or sharp edges are created or front/rear tips extenders become detached. Other risk factors include previous pelvic surgery, pelvic radiation, and spinal cord injury (Refs. 28 and 35).

Treatment of an eroded, migrated, or extruded device consists of removal of the device, antibiotic treatment, and supportive care (Refs. 21, 26, and 28). If the condition is not treated in a timely manner, the condition may worsen, leading to infection and loss of tissue (Ref. 21).

C. Mechanical Malfunction

As with other prosthetic devices intended to restore a physiologic function, penile rigidity implants may malfunction mechanically. Rates for mechanical malfunction vary with the type and model of penile rigidity implant, and are believed to be significantly lower now than they were with previous models due to improvements in design (Refs. 14, 17, and 27). Mechanical malfunction may be caused by improper device handling or surgical technique, or problems with the device's design or manufacturing process (Ref. 27).

Mechanical malfunctions may affect device effectiveness in terms of decreases in device positionability, implant rigidity or column strength, or length of the prosthesis (Refs. 1, 14, 19, 24, 25, and 36). Surgical intervention to remove and replace the device is required if the patient desires a working prosthesis (Refs. 1, 33, and 36).

D. Patient Dissatisfaction

If patients are not provided information and counseled about the risks and benefits of the penile rigidity implant prior to implantation, they may not have realistic expectations of the physical, psychological, and functional outcomes of the implant (Refs. 15, 26, and 30). Uninformed patients may be dissatisfied with the outcome in terms of size, shape, and rigidity of the prosthetic erection; concealability of the penis; penile scarring; penile sensation; the chance that any latent erectile capability will be lost following surgery; or other performance characteristics (Refs. 17, 21, 26, and 34). Some dissatisfied patients have requested removal of a device that was functioning according to the manufacturer's specifications because the implant did not meet their expectations (Refs. 9 and 22). With proper counseling, however, patient satisfaction with penile rigidity implants is typically in the range of 85

to 91 percent (Refs. 8, 12, 14, 16, 17, and 37).

E. Adverse Tissue Reaction

If the materials used in the construction of the device are not biocompatible, the patient may have an adverse tissue reaction. This risk is not unique to penile rigidity implants, as patients may have an adverse tissue or sensitivity reaction to any implanted device. Since the time that the penile rigidity implant was originally classified, few reports of adverse tissue reaction have been reported (Ref. 19). Surgical removal of the implant is generally indicated in patients experiencing prolonged discomfort or pain due to biocompatibility issues associated with device materials.

F. Prolonged or Intractable Pain

As would be expected for any implant, surgical placement of a penile rigidity implant results in temporary pain at the operative sites during the recovery period. Infrequently, however, cases of prolonged or intractable post-operative pain associated with device implantation have also been reported (Ref. 22). Persistent or worsening pain beyond the 4 to 6-week-post-operative healing period is symptomatic of possible infection (Refs. 23 and 29). However, studies have noted cases with persistent pain and subsequent device removal for which culture results were negative (Ref. 14). It is possible that pain can also be symptomatic of adverse tissue reaction, mechanical malfunction, or incorrect sizing of the device. Prolonged or intractable pain may lead to surgical intervention with device removal.

G. Urinary Obstruction

If the prosthesis compresses the urethra, urine flow could be impeded (Ref. 8). However, since the time that the penile rigidity implant was originally classified, reports of urinary obstruction secondary to implantation of a penile rigidity implant have been rare (Ref. 19). This complication may occur if the implant is improperly sized or malpositioned by the implanting physician. Surgical intervention may be indicated in patients experiencing urinary obstruction associated with the presence of the device.

H. Silicone Particle Migration

The patient-contacting surfaces of penile rigidity implants consist primarily of silicone elastomers. Neither silicone gel nor liquid are used in the construction of these devices. The migration of silicone particles from the solid elastomer exterior of various penile prostheses has been described by Barrett et al. (Ref. 2). Although particles of silicone were found in the tissues adjacent to the device and in draining lymph nodes in some patients, no deleterious effects have been associated with this finding to date. In a related study by Fishman et al., patients with pre-existing penile implants underwent pelvic lymph node dissection for reasons unrelated to the implant (Ref. 10). Microscopic examination of the lymph nodes showed no evidence of silicone elastomer migration.

Since the time that the reasons for placing penile rigidity implants into class III were first summarized, no adverse reactions related to silicone particle migration have been documented. Therefore, it appears that this theoretical risk may not be an actual risk of penile rigidity implants.

I. Other Complications

Other infrequently reported complications of the penile rigidity implant include post-operative bleeding, hematoma, penile edema, and penile necrosis/gangrene (Refs. 3, 19, 20, 26, and 36). Intraoperative complications have also been noted, which include perforation of the corpora or the urethra, inability to adequately dilate the corpora, incorrect sizing of the implant, and tearing or ripping the device during implantation (Refs. 5, 19, 26, 30, and 36). All of these complications can be reduced by good patient selection and careful surgical technique.

VI. Summary of Reasons for Reclassification

FDA believes the penile rigidity implant should be classified into class II because special controls, in addition to general controls, provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

VII. Summary of Data Upon Which the Reclassification is Based

In addition to the potential risks of the penile rigidity implant described in section V of this document, there is reasonable knowledge of the benefits of the device. Specifically, placement of the penile rigidity implant in men with erectile dysfunction typically provides sufficient penile rigidity for vaginal intercourse. Furthermore, satisfaction rates in excess of 90 percent have been reported among penile rigidity implant recipients (Refs. 8, 12, 14, 16, 17, and 37).

Based on the available information, FDA believes that the special controls discussed in section VIII of this document are capable of providing reasonable assurance of the safety and effectiveness of the penile rigidity implant with regard to the identified risks to health of this device.

VIII. Special Controls

In addition to general controls, FDA believes that the guidance document entitled, ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants'' (Ref. 38) is an adequate special control to address the risks to health described in section V of this document.

This guidance document addresses the following: (1) Physician labeling, (2) patient labeling, (3) biocompatibility testing, (4) mechanical testing, (5) clinical data requirements, and (6) sterilization procedures and labeling.

A. Physician labeling

The physician labeling section of the guidance document can help control the risks of infection, erosion, migration, extrusion, mechanical malfunction, patient dissatisfaction, prolonged or intractable pain, urinary obstruction, silicone particle migration, and other miscellaneous clinical complications by having the manufacturer provide information on: (1) The proper handling of the device prior to implantation, (2) selection and preparation of the patient, (3) surgical and sterile technique, (4) implant sizing, (5) care of the implant site during and after the recovery period, (6) post-operative use of the device, (7) how to recognize and minimize these potential complications, (8) the normal healing process, and (9) the realistic outcomes of the penile rigidity implant.

B. Patient labeling

The patient labeling section of the guidance document can help control the risks of infection, erosion, migration, extrusion, mechanical malfunction, patient dissatisfaction, prolonged or intractable pain, urinary obstruction, silicone particle migration, and other miscellaneous clinical complications by having the manufacturer provide prospective patients information on: (1) Care of the implant site during and after the recovery period, (2) post-operative use of the device, (3) how to recognize and minimize these potential complications, (4) the normal healing process, and (5) the realistic outcomes of the penile rigidity implant.

C. Biocompatibility testing

Adherence to the biocompatibility testing section of the guidance document can control the risk of

adverse tissue reaction by having the manufacturer demonstrate that the patient contacting materials of the penile rigidity implant are safe for long-term implantation.

D. Mechanical testing

Adherence to the mechanical testing section of the guidance document can help control the risks of erosion, migration, extrusion, and mechanical malfunction by demonstrating the reliability of the device.

E. Clinical data requirements

For penile rigidity implants that are significantly different from devices already on the market, the clinical data requirements section of the guidance document can help control the risks of infection, erosion, migration, extrusion, mechanical malfunction, and prolonged or intractable pain by determining whether these risks are within the limits established by existing devices.

F. Sterilization procedures and labeling

Adherence to the sterilization procedures and labeling section of the guidance document can help control the risk of infection by guarding against the implantation of an unsterile device.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 am. and 4 pm., Monday through Friday.

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39. Health Industry Manufacturers Association, 515(i) Submission of Safety and Effectiveness, Docket No. 94N–0417, August 14, 1996.
40. Mentor Corp., 515(i) Submission of Safety and Effectiveness, Docket No. 94N–0417, August 14, 1996.

X. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this proposed classification 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.

XI. 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 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 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 proposed 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 this device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, 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 the final rule will not have a significant economic impact on a substantial number of small entities. The rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year.

XII. Comments

Interested persons may, on or before March 16, 1998 submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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.

List of Subjects in 21 CFR Part 876

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 876 be amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

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

2. Section 876.3630 is revised to read as follows:

§ 876.3630 Penile rigidity implant.

(a) *Identification.* A penile rigidity implant is a device that consists of a pair of semi-rigid rods implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction. (b) *Classification.* Class II (special controls) (premarket notification guidance).

Dated: November 11, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–32809 Filed 12-15-97; 8:45 am]

BILLING CODE 4160–01–F

NATIONAL INDIAN GAMING COMMISSION

25 CFR Part 514

Annual Fees Payable By Indian Gaming Operations

AGENCY: National Indian Gaming Commission.

ACTION: Proposed rule.

SUMMARY: The National Indian Gaming Commission is proposing to amend its fee regulations to add class III gaming revenues to the assessable gross revenue base, increase the total amount of fees that can be imposed, and provide for an exemption for self-regulated tribes such as the Mississippi Band of Choctaw. This action is being taken pursuant to recent amendments to the Indian Gaming Regulatory Act. The primary effect of this action is to increase the funding for the National Indian Gaming Commission.

DATES: Comments must be submitted on or before January 15, 1998.

ADDRESSES: Comments may be mailed to: Fee Regulation Comments, National Indian Gaming Commission, 1441 L Street, N.W., Suite 9100, Washington, DC 20005, delivered to that address between 8:30 a.m. and 5:30 p.m., Monday through Friday, or faxed to 202/632–7066 (this is not a toll-free number). Comments received may be inspected between 9 a.m. and noon, and between 2 p.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Fred W. Stuckwisch at 202/632–7003; fax 202/632–7066 (these are not toll-free numbers).

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA), enacted on October 17, 1988, established the National Indian Gaming Commission (Commission). The Commission is charged with, among other things, regulating gaming on Indian lands. Pursuant to recent amendments to the IGRA, these fee regulations are being amended to:

(1) Add class III gaming revenues to the assessable gross revenue base,

(2) Increase the total amount of fees that can be imposed, and

(3) Provide an exemption for self-regulated tribes such as the Mississippi Band of Choctaw.

As a result, gaming operations offering only class III games must begin reporting and paying fees, and gaming operations offering both class II and III games must begin reporting and paying fees on their class III revenues.

The Commission has adopted a 30 day comment period for this proposed rule because (1) the basic rule has been in effect for six (6) years, (2) comments were received and considered before the basic rule was adopted, and (3) it is important that the increased funding for the Commission as enacted by Congress be implemented as soon as possible.

The purpose of these regulations is to implement those portions of IGRA that provide for the payment of fees by gaming operations and for the collection and use of such fees by the Commission. Gaming operations are the economic entities that are licensed by a tribe, operate the games, receive the revenues, issue the prizes, and pay the expenses. Gaming operations may be operated by a tribe directly, by a management contractor, or in the case of certain grandfathered class II gaming operations, by an individual owner/operator.

These regulations provide for a system of fee assessment and payment that is self-administered by the gaming operations. Briefly, the Commission adopts and communicates the assessment rates; the gaming operations apply those rates to their revenues, compute the fees to be paid, and report and remit the fees to the Commission on a quarterly basis.

Annual fees are payable quarterly each calendar year based on the previous calendar year's class II and III assessable gross revenues from the gaming operations.