DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99P–0895]

Gastroenterology-Urology Devices; Denial of Request for Change in Classification of Fiber Optic Light Sources

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; denial of petition.

SUMMARY: The Food and Drug Administration (FDA) is denying the petition submitted by QED, Inc. (QED) to reclassify fiber optic light sources used as accessories to endoscopes from class II to class I. The agency is denying the petition because QED failed to provide any new information to establish that general controls would provide reasonable assurance of the safety and effectiveness of the device. This notice also summarizes the basis for the agency's decision. 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), the Safe Medical Devices Act of 1990 (the SMDA), and the FDA Modernization Act of 1997 (the FDAMA).

EFFECTIVE DATE: November 3, 1999.

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

SUPPLEMENTARY INFORMATION:

I. Classification and Reclassification of Devices Under the 1976 Amendments

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), 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 control needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices under the 1976 amendments were class I (general controls), class II (performance standards), and class III (premarket approval). Except as provided in section 520(c) of the act (21 U.S.C. 360j(c)), FDA may not use confidential information concerning a device's safety and effectiveness as a basis for reclassification of the device from class III into class II or class I.

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 preamendment devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed 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.

Reclassification of classified preamendments devices is governed by section 513(e) of the act (21 U.S.C. 360c(e)). This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based on ''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 and 515(b)(2)(A)(iv) of the act (21 U.S.C. 360e(b)(2)(A)(iv)), 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 the 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 newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F.Supp. 382,389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the ''new information'' upon which reclassification under section 513(e) of the act is based must consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act (21 U.S.C. 360c(a)(3)) 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 a pending premarket approval application. (See section 520(c) of the act (21 U.S.C. 360j(c)).

II. Reclassification Under the SMDA

The SMDA (Public Law 101–629) further amended the act to change the definition of a class II device. Under the SMDA, class II devices are those devices which cannot be classified into class I because general controls by themselves are not sufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act (21 U.S.C. 360c(a)(1)(B)). Thus, the definition of the controls for a class II device was changed from ''performance standards'' to ''special controls.'' In order for a device to be reclassified from class II into class I, the agency must determine that special controls are not necessary to provide reasonable assurance of its safety and effectiveness.

III. Background

In the **Federal Register** of November 23, 1983 (48 FR 53012 at 53015), FDA issued a final rule classifying the endoscope and accessories, including fiber optic light sources, into class II (21 CFR 876.1500). The preamble to the proposal (46 FR 7571, January 23, 1981) to classify the device included the recommendations of the Gastroenterology-Urology Device and the General and Plastic Surgery Device Classification Panels (the Panels). Both Panels' recommendations, among other things, identified certain risks to health (misdiagnosis and inappropriate

therapy; infection; trauma, hemorrhage, or perforation; adverse tissue reaction; electrical injury because of improper design or construction; burns and rupture of body cavity, embolism and hypotensive shock) presented by the device. The agency agreed with both Panels' recommendations and proposed classification accordingly.

The agency received one comment on the proposed classification of the endoscope and accessories. The comment suggested that the endoscope and its accessories be classified into class I rather than class II as proposed. The comment stated that the skill of the user is more essential to the safe use of the device than its design and construction. The agency partially agreed with the comment. The agency believed that the principal hazard associated with the use of the device may be due to unskilled users. However, the agency believed then and continues to believe that fiber optic light sources should be classified into class II because the electrical, optical, mechanical, biocompatibility, and lighting characteristics of the device must be controlled by special controls to prevent injury to the patient resulting from devices of improper design and construction.

In the **Federal Register** of January 16, 1996 (61 FR 1117 at 1122), FDA issued a final rule reclassifying 111 generic types of class II devices into class I based on new information respecting such devices. FDA also exempted the 111 generic types of devices from the requirement of premarket notification, with limitations. Fourteen of the 111 generic types of devices were endoscopes and accessories, but did not include fiber optic light sources.

On December 11, 1998, the agency received a petition from QED, a consulting firm, requesting that the fiber optic light sources be reclassified from class II into class I.

IV. Device Description

A fiber optic light source is an accessory device to an endoscope that provides illumination to allow observation of body cavities, hollow organs, and canals.

V. Agency Decision

FDA recognizes that section 513(e) of the act provides that, for a preamendments device for which reclassification is sought, FDA may secure a recommendation concerning the reclassification of the device from the Panel which had made a recommendation on the initial classification of the device. FDA did not, however, refer this petition to the Panel because the petitioner did not present new information to warrant reconsideration of this device by a Panel.

The petition is requesting reclassification based, in part, on the European Union Medical Devices Directive 93/42 EEC (EU MDD), Annex IV, Classification III, Non-invasive Devices 1.1, Rule 1 and the FDA General Device Classification Questionnaire. According to the petition, the EU MDD would support down classifying these devices because it states that all noninvasive devices are class I unless particular exceptions apply and those exceptions are not relevant to the fiber optic light sources used as accessories for endoscopes. The petition also notes that the FDA questionnaire states that, ''if the device is not life supporting; is not a device for a use which is of substantial importance in preventing impairment of human health; does not present a potential unreasonable risk of illness or injury; and there is sufficient information to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness, then the device is class I.'' The petition implies that classification of the device into class I and the use of general controls are sufficient to provide reasonable assurance of safety and effectiveness.

Based on its review of the information contained in the petition, the agency finds that the petition raises the same issues that were evaluated by the device classification Panels and by FDA when issuing the 1983 final rule classifying the endoscope and accessories, including fiber optic light sources, into class II. The petitioner provided no new information to supports its claim that the risks posed by this device are of the type for which general controls alone would provide reasonable assurance of the safety and effectiveness of the device. Nor did the petitioner provide new information justifying a change in the classification of fiber optic light sources.

Furthermore, since the classification of this device, there have been technological advances in fiber optic light sources, i.e., many light sources are now software controlled. The petitioner provided no information as to how to control the risks associated with the software design. Additionally, at the time of the classification, electromagnetic compatibility (EMC) was not recognized as a risk to health. FDA now believes EMC should be considered a risk. Moreover, the agency searched its medical device reporting (MDR) data base in order to determine the extent of reported problems or adverse incidents associated with devices within this generic type. The search revealed several adverse events of the types considered by the Panels and FDA during and since the classification (Ref. 1). FDA believes that fiber optic light sources require special controls to eliminate or reduce the risks associated with them.

Accordingly, FDA believes, on the basis of the information considered in the petition, and for the same reasons stated when the classification regulation issued, as well as on the basis of technological advances and the MDR reports, that the risks to public health posed by these devices continue and that class II is necessary to provide a reasonable assurance of the safety and effectiveness of this type of device. Assuming the petitioner has correctly interpreted the EU MDD, the classification of a device under the EU regulatory system does not describe or establish a similar level of control under the act.

The petitioner's claim that ''light sources do not require special controls and are approved under the UL Safety Standards for Medical Devices, UL 2601'' does not support a reliance on general controls only; UL 2601 is the type of voluntary standard that would qualify as a special control. Similarly, the petitioner's claim that ''there is no potential hazard to the patient or the medical personnel'' because light sources conform to UL 2601 supports the agency's belief that electrical safety controls are needed for light sources.

As stated previously, FDA's search of the MDR data base revealed adverse events relating to electrical safety, such as arcing resulting in a burn; unintentional shutdown of the light source, resulting in a procedural delay; and patient and drape burns related to light cable guides. These are the type of adverse events which special controls are intended to obviate.

In further recognition of EMC and electrical safety risks, under the good guidance practices, FDA has developed a guidance document entitled ''510(k) Checklist for Endoscopic Light Sources Used in Gastroenterology and Urology,'' dated June 22, 1995. This checklist identifies the type of information a premarket notification should include to support a determination of substantial equivalence. The checklist also includes recommendations for EMC testing and electrical safety testing, including UL 2601 cited by the petitioner.

Under section 513(a)(1)(A) of the act, a device is to be classified in class I if it is a device for which the general controls are sufficient to provide reasonable assurance of the safety and

effectiveness of the device. Therefore, the relevant question is whether a device should be classified as class I and be subject only to general controls, or whether class II controls are necessary to provide reasonable assurance of the safety and effectiveness of the device. On the basis of information described previously concerning the risks associated with the fiber optic light sources, FDA believes that this device is appropriately in class II.

The petitioner presented no new information, in the form of valid scientific evidence, on which FDA could rely to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device for its intended use. FDA, therefore, is denying the petition.

VI. Reference

The following information has been placed on display in the Dockets Managements Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Food and Drug Administration, Center for Devices and Radiological Health, Medical Device Reporting Search Information, 5 pp.

Dated: September 9, 1999.

Linda S. Kahan,

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

[FR Doc. 99–28563 Filed 11–2–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pulmonary-Allergy Drugs 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). The meeting will be open to the public.

Name of Committee: Pulmonary-Allergy Drugs 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 November 22, 1999, 8 a.m. to 5 p.m. and November 23, 1999, 7:45 a.m. to 4 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8210 Wisconsin Ave., Bethesda, MD.

Contact Person: Leander B. Madoo, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12545. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 22, 1999, FDA will discuss its regulations related to ozone-depleting substances. In this discussion, FDA will review the Montreal Protocol on substances that deplete the ozone layer and the advanced notice of proposed rulemaking published on March 6, 1997 (62 FR 10242), as discussed at the April 11, 1997, committee meeting. FDA will provide an overview and detailed discussion of the proposed rule published on September 1, 1999 (64 FR 47719), related to the phase-out of chlorofluorocarbons (CFC's) in metered-dose inhalers. The proposed rule outlines the mechanism by which FDA will determine when the use of ozone-depleting substances, including CFC's in metered-dose, inhalers, in any product regulated by FDA is no longer essential under the Clear Air Act. The proposed rule can be downloaded at http://www.fda.gov/ohrma/dockets/98fr/090199b.pdf. FDA has also created a website at http://www.fda.gov/cder/mdi to provide information to the public regarding this proposal and the issues related to CFC use in medical products. The committee will discuss and comment on the proposed rule and on the presentations made during the public hearing.

On November 23, 1999, the committee will discuss the safety and efficacy of new drug application (NDA) 21–077 for three products: (1) Advair™ Diskus® 100 micrograms (µg) (salmeterol xinafoate 50 µg/fluticasone propionate 100 µg inhalation powder), (2) Advair™ Diskus® 250 µg (salmeterol xinafoate 50 µg/fluticasone inhalation powder), and (3) Advair™ Diskus® 500 µg (salmeterol xinafoate 50 µg/fluticasone propionate 500 µg inhalation powder), Glaxo Wellcome, for the maintenance treatment of asthma as prophylatic therapy in patients 12 years of age and older.

Procedure: 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 November 12, 1999. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 12:30 p.m. on November 22, 1999, and between approximately 8 a.m. and 8:30 a.m. on November 23, 1999. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 12, 1999, 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.

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

Dated: October 22, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–28559 Filed 11–2–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4491]

FDA's Proposed Strategy on Reuse of Single Use Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''FDA's Proposed Strategy on Reuse of Single-Use Devices.'' The document presents the agency's current thinking about the best way to address the concerns regarding the practice of reprocessing and reusing devices that are labeled, or otherwise intended, for one use only (referred to as ''single use devices'' (SUD's)). The strategy outlined in the document is based, in part, on information and suggestions the agency received during the May 5 and 6, 1999, conference on Reuse of Single-Use Devices, which the agency cosponsored with the Association for the Advancement of Medical Instrumentation (AAMI). The document reflects FDA's belief that the optimum approach to this issue will involve action by the agency and all of the affected stakeholders. The agency is soliciting comments, proposals for alternative approaches, and information on this issue. In a future issue of the **Federal Register**, the agency will announce an open meeting, to be held