(3) The applicant must also file with the Commission a copy of the initial description of its proposed project, each scoping document, and the preliminary draft environmental review document.

(4) All filings with the Commission under this section shall be made in the manner prescribed in §§ 157.6(a), 157.14(a) and 385.2011 of this chapter. The applicant shall send a copy of these filings to each participant that requests a copy.

(5) At a suitable location (or at more than one location if appropriate), the applicant will maintain a public file of all relevant documents, including scientific studies, correspondence, and minutes or summaries of meetings, compiled during the pre-filing collaborative process. The Commission will maintain a public file of the applicant's initial description of its proposed project, scoping documents, periodic reports on the pre-filing collaborative process, and the preliminary draft environmental review document.

(6) An applicant authorized to use the pre-filing collaborative procedures may substitute a preliminary draft environmental review document and additional material specified by the Commission instead of an environmental report with its application as required by § 380.3 of this chapter and need not supply additional documentation of the pre-filing collaborative process with its application. The applicant will file with the Commission the results of any studies conducted or other documentation as directed by the Commission, either on its own motion or in response to a motion by a party to the proceeding.

(7) Pursuant to the procedures approved, the participants will set reasonable deadlines requiring all resource agencies, Indian tribes, citizens' groups, and interested entities to submit to the applicant requests for scientific studies or alternative route analyses during the pre-filing collaborative process. Additional requests for studies may be made to the Commission after the filing of the application only for good cause shown.

(8) During the pre-filing collaborative process the Commission may require deadlines for the filing of preliminary resource agency recommendations, conditions, and comments, to be submitted in final form after the filing of the application.

(9) Any potential applicant, resource agency, Indian tribe, citizens' group, or other entity participating in the pre-filing collaborative process may file a request with the Commission to resolve a dispute concerning the process (including a dispute over required studies), but only after reasonable efforts have been made to resolve the dispute with other participants in the process. No such request will be accepted for filing unless the entity submitting it certifies that the request has been served on all other participants. The request must document what efforts have been made to resolve the dispute.

(g) If the potential applicant or any resource agency, Indian tribe, citizens' group, or other entity participating in the pre-filing collaborative process can show that it has cooperated in the process but that a consensus supporting the use of the pre-filing collaborative process no longer exists and that continued use of that process would not be productive, the participant may petition the Commission for an order directing the use by the potential applicant of appropriate procedures to complete its application. No such request will be accepted for filing unless the participant submitting it certifies that the request has been served on all other participants. The request must recommend specific procedures that are appropriate under the circumstances.

(h) The Commission staff may participate in the pre-filing collaborative process (and in discussions contemplating initiating a collaboration) and assist in the integration of this process and the environmental review process in any case. Commission staff positions are not binding on the Commission.

PART 375—THE COMMISSION

3. The authority citation for Part 375 continues to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 791–825r, 2601–2645; 42 U.S.C. 7101–7352.

4. In § 375.307, a new paragraph (h) is added, to read as follows:

§ 375.307 Delegations to the Director of the Office of Pipeline Regulation.

* * * * *

(h) Approve, on a case-specific basis, and make such decisions as may be necessary in connection with the use of pre-filing collaborative procedures, for the development of an application for certificate or abandonment authorization under section 7 of the Natural Gas Act, or the development of an application for facilities under section 3 of the Natural Gas Act, and assist in the pre-filing collaborative and related processes.

[FR Doc. 98–26720 Filed 10–6–98; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 98N–0753]

Dental Products Devices; Reclassification of Endosseous Dental Implant Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify manually powered drill bits, screwdrivers, countertorque devices, placement and removal tools, laboratory pieces used for fabrication of dental prosthetics, trial abutments, and other manually powered endosseous dental implant accessories from class III to class I. These devices are intended to aid in the placement or removal of endosseous implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. FDA also proposes to exempt these devices from premarket notification requirements. This reclassification is being proposed on the Secretary of Health and Human Services' 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), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments by January 5, 1999. 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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Angela E. Blackwell, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory authorities)

The act, as amended by the 1976 amendments (Pub. L. 94–295), the SMDA (Pub. L. 101–629), and FDAMA (Pub. L. 105–115), 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 postamendments 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: (1) The device is reclassified into class I or class II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) 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 part 807 (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.

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 newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F. Supp. 382, 389–391 (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 and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Association* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985).) 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 PMA. (See section 520(c) of the act (21 U.S.C. 360j(c)).) FDAMA added a new section 510(l) to the act. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury, hereafter these are referred to as ''reserved criteria.'' FDA has considered endosseous dental implant accessories in accordance with the reserved criteria and determined that the devices do not require premarket notification. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA.

II. Regulatory History of the Device

In the **Federal Register** of August 12, 1987 (52 FR 30082), FDA published a final rule (21 CFR 872.3640) classifying endosseous implants into class III. Endosseous dental implant accessories (drill bits, screwdrivers, countertorque devices, etc.), as accessories to endosseous implants, were also classified into class III (see section 201(h) of the act (21 U.S.C. 321(h)). The preamble to the proposal to classify the endosseous implants (45 FR 85962, December 30, 1980) identified certain risks the Dental Products Panel (the Panel) believed were presented by the implants. These risks included tissue degeneration, pain, bone perforation, and infection. On December 12, 1989, the Dental Implant Manufacturers Association (DIMA) submitted a petition requesting a change in the classification of certain endosseous implants from class III to class II. Subsequent to review of the petition and during a panel meeting (October 24, 1991), the Panel further identified paresthesia, perforation of the maxillary sinus, and the labia and lingual palates, and exfoliation as risks and voted to recommend denial of DIMA's petition. Additionally, FDA identified local and systemic infection and implant failure as significant risks associated with endosseous implants. However, none of these risks were directly related to the accessories.

During subsequent panel meetings on November 4, 1997, and January 13, 1998, the Panel, after reviewing safety and effectiveness data submitted by manufacturers at FDA's request, considered the reclassification of dental implants and abutments. The Panel recommended the reclassification of root form implants from class III to class II with special controls that include education, a precautionary statement regarding use in growing individuals (labeling), standards, guidance documents, and clinical trials. The Panel further recommended that blade implants remain in class III. Regarding abutments, the Panel recommended that premanufactured prosthetic components (abutments) which are connected directly to an implant be reclassified from class III to class II and codified separately. FDA intends to address the classification of dental implants and

premanufactured prosthetic components in a separate rulemaking.

In accordance with section 513(e) of the act and 21 CFR 860.130(a)(1), based on new information with respect to these devices, FDA, on its own initiative, is proposing to reclassify endosseous dental implant accessories from class III to class I when intended to aid in the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous dental implants and abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implant when tissue contact will last less than 1 hour.

III. Device Description

Endosseous dental implant accessories are manually powered devices intended to aid in the placement or removal of endosseous implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. These devices include drill bits, screwdrivers, countertorque devices, placement and removal tools, and laboratory pieces used for fabrication of dental prosthetics and trial abutments. These devices are made from materials currently in use in endosseous implant dentistry.

Some accessory devices that may be associated with endosseous dental implants may be classified under a different regulation. For example, drill bits for uses other than with implants are classified as dental burs (21 CFR 872.3240). Some other devices, when used for dental procedures other than with implants are considered dental hand instruments (21 CFR 872.4565). These burs and hand held instruments are currently class I devices and are exempt from the 510(k) procedures. When these dental burs and hand held instruments are used as accessories for endosseous dental implants, they now would be classified under proposed 21 CFR 872.3980. Under the proposal, these accessory devices would also be class I and exempt from the 510(k) procedures.

IV. Proposed Reclassification

FDA is proposing that endosseous dental implants accessories intended to aid in the placement or removal of endosseous dental implants and abutments, prepare the site for placement of endosseous implants and abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour should be reclassified from class III to class I. FDA believes that class I would provide reasonable assurance of safety and effectiveness. FDA also proposes that the devices be exempt from premarket notification requirements.

V. Risks to Health

When endosseous implants were classified into class III (52 FR 30082), the Panel and FDA identified several risks (tissue degeneration, pain, bone perforation, and infection) associated with them. Subsequent to the classification, additional data and information became available. Based on a review of the new data and information, other risks were identified. These ''other'' risks included local soft tissue degeneration and bone resorption, paresthesia, nerve impingement, perforation of the maxillary sinus, perforation of the labia and lingual palates, exfoliation, local and systemic infection, and implant failure. FDA believes that these risks associated with endosseous implants are not attributable in any significant way to the accessories used by the clinician to implant the device. FDA, therefore, believes there are minimal risks to health posed by the reclassification of these accessories.

VI. Summary of Reasons for the Reclassification

FDA believes that endosseous dental implant accessories should be classified into class I because general controls would provide reasonable assurance of safety and effectiveness. Furthermore, FDA believes these accessories are exempt from 510(k) requirements under the act. FDAMA added a new section 510(l) to the act. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury, hereafter referred to as ''reserved criteria.'' Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA.

FDA has considered the endosseous dental implant accessories in accordance with the reserved criteria and determined that the devices do not require premarket notification. These devices are designed for use in dental implant surgery and by clinicians trained in their use. These devices do not have a history of risks associated with them. FDA further believes that manufacturers' adherence to current good manufacturing practices (CGMP's) in the quality system regulation will provide reasonable assurance of the safety and effectiveness of these devices.

VII. Summary of Data Upon Which the Reclassification is Based

When endosseous implants were classified, endosseous dental implant accessories were considered in conjunction with the implants and were not independently addressed. As a result, the classification of the endosseous implants included the accessories. Since that time, FDA has reevaluated endosseous implants and endosseous dental implant accessories and now believes the risks associated with the implants listed in section V of this document under ''Risks to Health'' are not significantly attributable to the accessories. The risks identified previously relate to the skill of the clinician inserting the implant and the individual patient's ability to tolerate and maintain such implantation. Tissue degeneration, e.g., is caused by pressure from the implant transferring to the soft tissue and causing soft tissue resorption. Pain is caused by implant placement or nerve impingement. Bone perforation is due primarily to individual patient physiology and inadequate monitoring of patient selection for such procedures; the implant may perforate the ridge of the mandible or maxilla because the ridge is too thin. Infection is cause by microbial contamination of dental tissue compromised by degeneration or bone perforation. Paresthesia is caused by disturbing the neurovascular bundle during implant placement. Perforation of the maxillary sinus and perforation of the bony structures occur when the implant does not integrate. A fibrous pocket around an implant can cause mobility and implant loss. As stated previously, these risks are associated with the endosseous dental implant and not the accessories.

The accessory devices that are the subject of this rule are intended for use by trained clinicians. Trauma to a patient's oral cavity from use of one of the devices is essentially controlled by the skills of the clinician using it. The device itself would rarely be responsible for the trauma. FDA believes that a minimal risk to health would result if these accessories were to have an

improper design. FDA believes that manufacturers' adherence to the requirements of the CGMP's would provide reasonable assurance of safety and effectiveness. In light of the new information, FDA believes that the general controls of class I would provide reasonable assurance of safety and effectiveness of the endosseous dental implant accessories for their intended use.

VIII. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this 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.

IX. 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 these devices from class III to class I 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 these devices, 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 this proposed rule, if issued, will not have a significant ecomomic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XI. Submission of Comments

Interested persons may, on or before January 5, 1999, 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 872

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 872 in subpart D be amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

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

2. Section 872.3980 is added to subpart D to read as follows:

§ 872.3980 Endosseous dental implant accessories.

(a) *Identification*. Endosseous dental implant accessories are manually powered devices intended to aid in the placement or removal of endosseous implants and abutments, prepare the site for placement of endosseous dental implants or abutments, aid in the fitting of endosseous dental implants or abutments, aid in the fabrication of dental prosthetics, and be used as an accessory with endosseous dental implants when tissue contact will last less than 1 hour. These devices include drill bits, screwdrivers, countertorque devices, placement and removal tools, laboratory pieces used for fabrication of dental prosthetics and trial abutments. These devices are made from materials currently in use in endosseous implant dentistry.

(b) *Classification*. Class I (general controls). The device is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

Dated: September 26, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–26816 Filed 10–6–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 53

[REG–246256–94]

RIN 1545–AV60

Failure by Certain Charitable Organizations to Meet Certain Qualification Requirements; Taxes on Excess Benefit Transactions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains a correction to REG–245256–94, which was published in the **Federal Register** on Tuesday, August 4, 1998 (63 FR 41486), relating to the excise taxes on excess benefit transactions.

FOR FURTHER INFORMATION CONTACT: Phyllis D. Haney, (202) 622–4290 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This notice of proposed rulemaking that is the subject of this correction is under section 4958 of the Internal Revenue Code.

Need for Correction

As published, REG–246256–96 contains an error which may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking (REG–246256–96), which is the subject of FR Doc. 98–20419, is corrected as follows:

§ 53.4958–4 [Corrected]

On page 41502, column 1, § 53.4958–4(b)(3)(iii), *Example 2*, ninth line from the bottom of the paragraph, the language ''determination of whether N's compensation'' is corrected to read