their labeling when ordering new product labeling to be in compliance with the OTC antidiarrheal drug products FM. Adding this claim might result in additional product sales but, in any case, is completely optional. Thus, this final rule will not impose a significant economic burden on affected entities. Therefore, FDA certifies that this final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required under the Regulatory Flexibility Act (5 U.S.C. 605(b)).

V. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this document are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Environmental Impact

FDA has determined under 21 CFR 25.31(a) 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.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency concludes that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 335

Labeling, Over-the-counter drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 335 is amended as follows:

PART 335—ANTIDIARRHEAL DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

■ 1. The authority citation for 21 CFR part 335 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

■ 2. Section 335.3 is amended by adding paragraph (c) to read as follows:

§ 335.3 Definitions.

* * * * *

(c) *Travelers' diarrhea.* A subset of diarrhea occurring in travelers that is most commonly caused by an infectious agent.

■ 3. Section 335.50 is amended by revising paragraph (b)(1) to read as follows:

§ 335.50 Labeling of antidiarrheal drug products.

* * * * *

(b) * * *

(1) *For products containing bismuth subsalicylate identified in § 335.10(a).* The labeling states [select one of the following: ''controls'' or ''relieves''] [select one or both of the following: ''diarrhea'' or ''travelers' diarrhea'']. If both ''diarrhea'' and ''travelers' diarrhea'' are selected, each shall be preceded by a bullet in accordance with § 201.66(b)(4) and (d)(4) of this chapter and the heading ''Uses'' shall be used.

* * * * *

Dated: May 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–10750 Filed 5–11–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 2002N–0114]

Dental Devices; Reclassification of Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying root-form endosseous dental implants and endosseous dental implant abutments from class III to class II (special controls). Root-form endosseous dental implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Endosseous dental implant abutments are separate components that are attached to the dental implant and intended to aid in prosthetic rehabilitation. FDA is reclassifying these devices on its own initiative on the basis of new information. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for these devices. FDA is taking this action 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 Food and Drug Administration Modernization Act of 1997, and the Medical Device User Fee and Modernization Act of 2002.

DATES: This rule is effective June 11, 2004.

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, 301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et seq.*) 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, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as ''preamendments devices.'' FDA classifies these devices after the agency initiates the following procedures: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as ''postamendments devices.''

These devices are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. The devices remain in class III and require premarket approval, unless FDA initiates the following procedures: (1) Reclassifies the device into class I or II; (2) issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act; or (3) issues, under section 513(i) of the act, an order finding the device substantially equivalent to a predicate device that does not require premarket approval. As described in section 510(k) of the act (21 U.S.C. 360(k)) and under part 807 of the regulations (21 CFR part 807), FDA determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures. Through premarket notification procedures, a person may, without submission of a premarket approval application (PMA), market a preamendments device that has been classified into class III until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 513(e) of the act governs the reclassification of classified preamendments devices. This section provides that FDA may, by rulemaking, reclassify a device based on ''new information.'' Under section 513(e) of the act, FDA can initiate reclassification or an interested person can petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the act, includes information developed after the date of the device's original classification. This information could include a reevalution of the original data or information from the time of the device's original classification that was not presented, available, or 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 used by FDA 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, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Whether data before the FDA are past or new data, the ''new information'' to support reclassification under section 513(e) must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* 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. When reclassifying a device, FDA can only consider valid scientific evidence that is publicly available. Publicly available information excludes trade secret and confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).)

II. Regulatory History of the Device

In the **Federal Register** of May 14, 2002 (67 FR 34416), FDA proposed to reclassify root-form endosseous dental implants and endosseous dental implant abutments from class III to class II (special controls). Root-form endosseous dental implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Endosseous dental implant abutments are separate components that are attached to the dental implant and intended to aid in prosthetic rehabilitation. Blade-form endosseous dental implants remain in class III and will require the filing of a PMA or product development protocol at a future date.

Also in the **Federal Register** of May 14, 2002 (67 FR 34458), FDA announced the availability of a draft guidance document that FDA intended to serve as the special control for root-form endosseous dental implants and endosseous dental implant abutments, if FDA reclassified them. FDA gave interested persons until August 12, 2002, to comment on the proposed regulation and special controls draft guidance document. FDA received a total of five comments on the proposed regulation and draft guidance document.

III. Summary of Final Rule

In accordance with § 860.84(g)(2) of the regulations, FDA is reclassifying root-form endosseous dental implants and endosseous dental implant abutments into class II. FDA is revising the classification of endosseous implants to distinguish between root-form endosseous dental implants and blade-form endosseous dental implants. Root-form endosseous dental implants are characterized by four geometrically distinct types: Basket, screw, solid cylinder, and hollow cylinder. Blade-form endosseous dental implants are flat and have different surgical requirements. To ensure clarity, FDA is establishing a separate classification regulation for endosseous dental implant abutments (§ 872.3630 (21 CFR 872.3630)), because abutments are not implants. The guidance document entitled ''Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments'' will serve as the special control for both devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of this guidance. Following the effective date of the final classification rule, any firm submitting a 510(k) premarket notification for these devices will need to address the issues covered in the special controls guidance document. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA believes that review of performance characteristics and labeling can ensure that acceptable levels of performance for both safety and effectiveness are addressed before marketing clearance. Persons who intend to market these devices must submit to FDA a premarket notification submission before marketing the devices.

IV. Analysis of Comments and FDA's Response

FDA received a total of five comments on the proposed rule and the special controls guidance document. Four comments addressed reclassification. Three comments agreed with the reclassification of root-form endosseous dental implants from class III to class II. One comment stated that root-form endosseous dental implants should remain in class III because of the potential for initial contamination of an implant at placement. The comment believes that initial contamination of the implant may be a cause of oral infection resulting in the future loss of the implant. FDA believes that the quality system regulation requirements, a general control, along with the recommended mitigation measures for health risks specified in the special controls guidance document, address sterility issues adequately and provide reasonable assurance of safety and effectiveness. Therefore, FDA is codifying the reclassification of root-form endosseous dental implants by revising § 872.3640.

Three comments supported the reclassification of endosseous dental

implant abutments into class II. FDA is codifying the reclassification of endosseous dental implant abutments in a separate classification regulation (§ 872.3630). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for both devices.

V. Environmental Impact

FDA has determined under 21 CFR 25.34(b) that this reclassification action 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.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives. If regulation is necessary, a regulatory agency must plot a course that maximizes net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA believes the final rule is consistent with the regulatory philosophy and principles identified in the Executive order. Additionally, as defined by the Executive order, the final rule does not constitute a significant regulatory action. As a result, the final rule 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 II will relieve all manufacturers of the devices of the cost of eventually complying with the premarket approval requirements in section 515 of the act. FDA expects that manufacturers of cleared root-form endosseous dental implants and endosseous dental implant abutments will not have to take any additional action in response to this rule. Currently, manufacturers of endosseous dental implants and endosseous dental implant abutments must submit premarket notifications to FDA before marketing their devices. The guidance document reflects existing FDA practice in the review of these premarket notifications and will help expedite the review process for new manufacturers of these devices. Because reclassification will reduce the regulatory costs associated with these devices, it will impose no new burdens on manufacturers of these devices. In fact, it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate. As a result, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VII. Federalism

FDA has analyzed the final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies conferring substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order. As a result, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

FDA concludes that the final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget, according to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

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, 21 CFR part 872 is 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 872.3630 is added to subpart D to read as follows:

§ 872.3630 Endosseous dental implant abutment.

(a) *Identification*. An endosseous dental implant abutment is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

(b) *Classification*. Class II (special controls). The guidance document entitled ''Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments'' will serve as the special control. (See § 872.1(e) for the availability of this guidance document.)

■ 3. Section 872.3640 is revised to read as follows:

§ 872.3640 Endosseous dental implant.

(a) *Identification*. An endosseous dental implant is a device made of a material such as titanium or titanium alloy, that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.

(b) *Classification*. (1) Class II (special controls). The device is classified as class II if it is a root-form endosseous dental implant. The root-form endosseous dental implant is characterized by four geometrically distinct types: Basket, screw, solid cylinder, and hollow cylinder. The guidance document entitled ''Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments'' will serve as the special control. (See § 872.1(e) for the availability of this guidance document.)

(2) Class III (premarket approval). The device is classified as class III if it is a blade-form endosseous dental implant.

Dated: May 3, 2004.

Linda S. Kahan,

Center for Devices and Radiological Health.

[FR Doc. 04–10748 Filed 5–11–04; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9124]

RIN 1545–BA69

At-Risk Limitations; Interest Other Than That of a Creditor; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contain a correction to final regulations that were published in the **Federal Register** on