

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

Monday, May 3, 2004 (69 FR 24078) relating to the treatment, for purposes of the at-risk limitations, of amounts borrowed from a person who has an interest in an activity other than that of a creditor or from a person (other than the borrower) with such an interest.

DATES: This correction is effective May 3, 2004.

FOR FURTHER INFORMATION CONTACT: Tara P. Volungis or Christopher L. Trump, (202) 622-3070 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that is the subject of this correction is under section 465 of the Internal Revenue Code.

Need for Correction

As published, the final regulation contains an error that may prove to be misleading and is in need of clarification.

Correction of Publication

■ Accordingly, the publication of the final regulations (TD 9124), that were the subject of FR Doc. 04-10010, is corrected as follows:

§ 1.465-8 [Corrected]

■ In § 1.465-8(b)(4), *Example 1.*, the language, “\$30,000 payable to A. The three partners, B, C, and D, each assumes personal liability for”. is corrected to read “\$30,000 payable to A. Each of the three partners, B, C, and D, assumes personal liability for”.

Cynthia E. Grigsby,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedures and Administration).

[FR Doc. 04-10789 Filed 5-11-04; 8:45 am]

BILLING CODE 4830-01-P

POSTAL SERVICE

39 CFR Part 111

Permissible Barcode Symbology for Parcels Eligible for the Barcode Discount

AGENCY: Postal Service.

ACTION: Withdrawal of final rule.

SUMMARY: We are withdrawing the amendment to the Domestic Mail Manual in the final rule published in the **Federal Register** on May 6, 2004 [69 FR 25321], that announced a new requirement for Package Services parcels.

EFFECTIVE DATE: May 12, 2004.

FOR FURTHER INFORMATION CONTACT: Obataiye B. Akinwale at (703) 292-3643.

SUPPLEMENTARY INFORMATION: The Postal Service will issue a further document regarding these mailing standards.

Neva R. Watson,

Attorney, Legislative.

[FR Doc. 04-10848 Filed 5-10-04; 12:33 pm]

BILLING CODE 7710-12-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-2004-0094; FRL-7358-2]

Pyraflufen-ethyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of pyraflufen-ethyl, (ethyl 2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetate) and its acid metabolite, E-1 (2-chloro-5-(4-chloro-5-difluoromethoxy-1-methyl-1H-pyrazol-3-yl)-4-fluorophenoxyacetic acid), in or on wheat, forage; wheat, grain; wheat, hay; and wheat, straw. Nichino America Incorporated requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective May 12, 2004. Objections and requests for hearings must be received on or before July 12, 2004.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under Docket ID number OPP-2004-0094. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket

facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6224; e-mail address: miller.joanne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers; dairy cattle farmers; livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>.