

(3) The routine uses FHFA or FHFA-OIG may make of the information; and

(4) The effects on the individual, if any, of not providing the information.

(d) Ensure that the employee's office does not maintain a system of records without public notice and notify appropriate officials of the existence or development of any system of records that is not the subject of a current or planned public notice;

(e) Maintain all records that are used in making any determination about an individual with such accuracy, relevance, timeliness, and completeness as is reasonably necessary to ensure fairness to the individual in the determination;

(f) Except for disclosures made under FOIA, make reasonable efforts, prior to disseminating any record about an individual, to ensure that the record is accurate, relevant, timely, and complete;

(g) When required by the Privacy Act, maintain an accounting in the specified form of all disclosures of records by FHFA or FHFA-OIG to persons, organizations, or Federal agencies;

(h) Maintain and use records with care to prevent the unauthorized or inadvertent disclosure of a record to anyone; and

(i) Notify the appropriate official of any record that contains information that the Privacy Act does not permit FHFA or FHFA-OIG to maintain.

§ 1204.11 May FHFA-OIG obtain Privacy Act records from other Federal agencies for law enforcement purposes?

(a) The FHFA Inspector General is authorized under the Inspector General Act of 1978, as amended, to make written requests under 5 U.S.C. 552a(b)(7) for transfer of records maintained by other Federal agencies which are necessary to carry out an authorized law enforcement activity under the Inspector General Act of 1978, as amended.

(b) The FHFA Inspector General delegates the authority under paragraph (a) of this section to the following FHFA-OIG officials—

- (1) Principal Deputy Inspector General;
- (2) Deputy Inspector General for Audits;
- (3) Deputy Inspector General for Investigations;
- (4) Deputy Inspector General for Evaluations; and
- (5) Deputy Inspector General for Administration.

(c) The officials listed in paragraph (b) of this section may not further delegate or re-delegate the authority described in paragraph (a) of this section.

Dated: August 11, 2011.

Edward J. DeMarco,

Acting Director, Federal Housing Finance Agency.

[FR Doc. 2011-21250 Filed 8-18-11; 8:45 am]

BILLING CODE 8070-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA-2011-M-0570]

Medical Devices; Ophthalmic Devices; Classification of the Eyelid Thermal Pulsation System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the eyelid thermal pulsation system into class II (special controls). The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This rule is effective September 19, 2011. The classification was effective on June 28, 2011.

FOR FURTHER INFORMATION CONTACT: Marc Robboy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2256, Silver Spring, MD 20993-0002, 301-796-6860.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C 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 predicate devices by means of premarket notification procedures in

section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act. FDA will, within 60 days of receiving this request, classify the device by written order. This classification will be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on July 12, 2010, classifying the LipiFlow® Thermal Pulsation System into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On August 6, 2010, TearScience, Inc., submitted a petition requesting classification of the LipiFlow® Thermal Pulsation System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II. (Ref. 1)

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name eyelid thermal pulsation system, and it is identified as an electrically-powered device intended for use in the application of localized heat and pressure therapy to the eyelids. The device is used in adult patients with chronic cystic conditions of the eyelids,

including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye. The system consists of a component that is inserted around the eyelids and a component to control the application of heat and pressure to the eyelids.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks:

Identified risk	Mitigation measures
Infection	Sterility and Shelf Life Testing. Biocompatibility.
Adverse tissue reaction.	
Electrical shock	Electrical Safety Testing.
Electromagnetic interference.	Electromagnetic Compatibility (EMC) Testing; Labeling.
Thermal damage	Temperature Performance Testing.
Mechanical damage ..	Pressure Performance Testing.
Malfunction	Non-clinical and Clinical Performance Testing.
User error	Labeling.

FDA believes that the following special controls can address these risks to health and provide reasonable assurance of safety and effectiveness: (1) Appropriate analysis/testing should validate electromagnetic compatibility (EMC) and safety of exposure to non-ionizing radiation; (2) Design, description, and performance data should validate safeguards related to the temperature and pressure aspects of the device, including during fault conditions; (3) Performance data should demonstrate the sterility of patient-contacting components and the shelf-life of these components; (4) The device should be demonstrated to be biocompatible; and (5) Performance data should demonstrate that any technological changes do not adversely affect safety and effectiveness. Therefore, on June 28, 2011, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying the classification of the device by adding § 886.5200.

Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for an eyelid thermal pulsation system will need to comply with the special controls named in the regulation.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that

premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the eyelid thermal pulsation system they intend to market.

II. 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct 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 final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of this device from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the FD&C act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may

result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to “construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain state requirements “different from or in addition to” certain Federal requirements applicable to devices. (See section 521 of the FD&C Act (21 U.S.C. 360k) *Medtronic Inc., v. Lohr*, 518 U.S. 470 (1996); *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008)). The special controls established by this final rule create “requirements” for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. See *Papike v. Tambrands, Inc.*, 107 F. 3d 737, 740–42 (9th Cir. 1997).

V. Paperwork Reduction Act of 1995

This final rule establishes special controls that refer to currently approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 32501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

VI. References

The following references have been placed on display in the Division of Dockets Management (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. Petition from TearScience, Inc., August 6, 2010.

List of Subjects in 21 CFR Part 886

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 886 is amended as follows:

PART 886—OPHTHALMIC DEVICES

- 1. The authority citation for 21 CFR part 886 continues to read as follows:

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

- 2. Section 886.5200 is added to subpart F to read as follows:

§ 886.5200 Eyelid thermal pulsation system.

(a) *Identification.* An eyelid thermal pulsation system is an electrically-powered device intended for use in the application of localized heat and pressure therapy to the eyelids. The device is used in adult patients with chronic cystic conditions of the eyelids, including meibomian gland dysfunction (MGD), also known as evaporative dry eye or lipid deficiency dry eye. The system consists of a component that is inserted around the eyelids and a component to control the application of heat and pressure to the eyelids.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing should validate electromagnetic compatibility (EMC) and safety of exposure to non-ionizing radiation;

(2) Design, description, and performance data should validate safeguards related to the temperature and pressure aspects of the device, including during fault conditions;

(3) Performance data should demonstrate the sterility of patient-contacting components and the shelf-life of these components;

(4) The device should be demonstrated to be biocompatible; and

(5) Performance data should demonstrate that any technological changes do not adversely effect safety and effectiveness.

Dated: August 12, 2011.

Nancy K. Stade,

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

[FR Doc. 2011-21195 Filed 8-18-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9538]

RIN 1545-BK14

Modifications of Certain Derivative Contracts; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final and temporary regulations.

SUMMARY: This document describes corrections to final and temporary regulations (TD 9538) that address when a transfer or assignment of certain derivative contracts does not result in an exchange to the nonassigning counterparty for purposes of § 1.1001-1(a). These regulations were published in the **Federal Register** on Friday, July 22, 2011.

DATES: This correction is effective on August 19, 2011, and is applicable on July 22, 2011.

FOR FURTHER INFORMATION CONTACT: Andrea M. Hoffenson, (202) 622-3920 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of this correction are under section 1001 of the Internal Revenue Code.

Need for Correction

As published July 22, 2011 (76 FR 43892), final and temporary regulations (TD 9538) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final and temporary regulations (TD 9538) which were the subject of FR Doc. 2011-18529 is corrected as follows:

1. On page 43892, column 3, in the preamble, under the paragraph heading “Explanation of Provisions”, first paragraph of the column, lines 5, 6, and 7, the language “in securities or a clearinghouse transfers or assigns a derivative contract to another dealer in securities or” is corrected to read “or a clearinghouse transfers or assigns a derivative contract to another dealer or”.

2. On page 43892, column 3, in the preamble, under the paragraph heading “Explanation of Provisions”, first paragraph of the column, lines 12 and 13, the language “those described in

section 475(c)(2)(D), 475(c)(2)(E), or 475(c)(2)(F). In addition,” is corrected to read “those described in sections 475(c)(2)(D), 475(c)(2)(E), 475(c)(2)(F), 475(e)(2)(B), 475(e)(2)(C), or 475(e)(2)(D), or § 1.446-3(c)(1). In addition,”.

3. On page 43892, column 3, in the preamble, under the paragraph heading “Special Analyses”, the last line of the paragraph, the language “on their impact on small business.” is corrected to read “on their impact on small businesses.”.

LaNita Van Dyke,

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

[FR Doc. 2011-21179 Filed 8-18-11; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9538]

RIN 1545-BK14

Modifications of Certain Derivative Contracts; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document describes correcting amendments to final and temporary regulations (TD 9538) that address when a transfer or assignment of certain derivative contracts does not result in an exchange to the nonassigning counterparty for purposes.

These regulations were published in the **Federal Register** on Friday, July 22, 2011.

DATES: This correction is effective on August 19, 2011, and is applicable beginning July 22, 2011.

FOR FURTHER INFORMATION CONTACT: Andrea M. Hoffenson, (202) 622-3920 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final and temporary regulations that are the subject of this correction are under section 1001 of the Internal Revenue Code.

Need for Correction

As published July 22, 2011 (76 FR 43892), the final and temporary regulations (TD 9538) contain errors that may prove to be misleading and are in need of clarification.