



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. FDA-2013-N-0069]

Medical Devices; Ophthalmic Devices; Classification of the Eyelid Weight

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify the eyelid weight into class II (special controls). The eyelid weight may be adhered to the outer skin of the upper eyelid (external eyelid weight) or implanted into the upper eyelid (implantable eyelid weight), and is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure). FDA is also giving notice of its intent to exempt the external eyelid weight device from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act). After considering public comments on the proposed classification, FDA will publish a final regulation classifying this device type.

DATES: Submit either electronic or written comments by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section IV of this document for the proposed effective date of a final rule that may issue based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-0069, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following way:

- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2013-N-0069 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory and Regulatory Authorities

The FD&C Act (21 U.S.C. 301 et seq.), as amended by the Medical Device Amendments of 1976 (Public Law 94-295), the Safe Medical Devices Act of 1990 (Public Law 101-629), and the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C 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 FD&C Act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), as “preamendments devices.” FDA classifies these devices after the Agency takes the following steps:

- Receives a recommendation from a device classification panel (an FDA advisory committee);
- publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and
- publishes a final regulation classifying the device.

FDA has classified most preamendments devices under these procedures.

A person may market a preamendments device that has been classified into class III through premarket notification procedures, without submission of a premarket approval application until FDA publishes a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 510(m) of the FD&C Act (21 U.S.C. 360(m)) provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of the external eyelid weight.

B. Regulatory History of the Device

After the enactment of the Medical Device Amendments of 1976, FDA commenced to identify and classify all preamendments devices, in accordance with section 513(b) of the FD&C Act. In the Federal Register of September 2, 1987 (52 FR 33346), FDA classified a total of 109 generic types of ophthalmic devices. The eyelid weight was not identified in this initial effort. FDA has regulated eyelid weights as devices requiring premarket notification (section 510(k) of the FD&C Act). Eyelid weights currently on the market have been determined to be substantially equivalent to devices that were in commercial distribution prior to May 28, 1976.

Consistent with the FD&C Act and the regulations, FDA consulted with the Ophthalmic Devices Panel (the Panel), an FDA advisory committee, regarding the classification of this device type on January 13 and 14, 2000 (Ref. 1).

II. Panel Recommendation

A. Identification

An eyelid weight is a prescription device made of gold, tantalum, platinum, iridium, or surgical grade stainless steel that is rectangular in shape and contoured to the shape of the eye. The device is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure). The external eyelid weight is adhered to the outer skin of the upper eyelid. The implantable eyelid weight is implanted into the upper eyelid.

B. Recommended Classification of the Panel

The Panel recommended that the eyelid weight, both external and implantable, be classified into class II. The Panel also recommended that the external eyelid weight be exempt from premarket notification requirements. The Panel believed that class II classification (with special controls appropriate for the external eyelid weight and special controls appropriate for the implantable eyelid weight) would provide reasonable assurance of the safety and effectiveness of the device.

C. Summary of Reasons to Support the Proposed Panel Recommendation

The Panel considered information from the scientific literature review conducted by FDA, FDA's extensive regulatory experience with the device type, and the Panel members' personal knowledge of and clinical experience with the device type. The Panel also considered the long history of safety and effectiveness of the device, both external and implantable, over many years of clinical use. The Panel recommended that the eyelid weight, external and implantable, be classified into class II because the Panel concluded that special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device type, and that there is sufficient information to establish special controls to provide

such assurance for both the external and implantable eyelid weight. The Panel also recommended that the external eyelid weight be exempt from premarket notification requirements, while the implantable eyelid weight would not be exempt from premarket notification.

D. Risks to Health and Special Controls

Based on the Panel's discussion and recommendations and FDA's experience with the device, the risks to health associated with the external eyelid weight and the proposed measures to mitigate these risks are identified in table 1 of this document; the risks to health associated with the implantable eyelid weight and the proposed measures to mitigate these risks are identified in table 2 of this document.

Table 1.--Health Risks and Mitigation Measures for the External Eyelid Weight

Identified Risk	Mitigation Measures
Mild adverse tissue reaction	Biocompatibility testing and labeling
Magnetic resonance (MR) incompatibility	Nonclinical testing and labeling
Temporary induced astigmatism (which can result in blurred vision requiring glasses)	Labeling
Ptosis (droopy eyelid)	Labeling

Risks associated with the use of the external eyelid weight are related to the placement of the device and the material of which it is composed. Biocompatibility testing will mitigate the risk of mild adverse tissue reaction; nonclinical testing will mitigate the risk of MR incompatibility; labeling will mitigate the risks of mild adverse tissue reaction, temporary induced astigmatism, and ptosis, and communicate potential MR incompatibility.

FDA believes that the following special controls, in addition to general controls, can address the risks to health in table 1 of this document and provide reasonable assurance of safety and effectiveness of the device: (1) Testing demonstrating the biocompatibility of the device; (2) and nonclinical testing evaluating the compatibility of the device in a MR environment. In

addition, under 21 CFR 801.109, the sale, distribution, and use of the device are restricted to prescription use.

Table 2.--Health Risks and Mitigation Measures for the Implantable Eyelid Weight

Identified Risk	Mitigation Measures
Adverse tissue reaction	Biocompatibility testing and labeling
Device migration	Biocompatibility testing and labeling
Extrusion through the eyelid	Biocompatibility testing and labeling
Infection	Sterility testing
MR incompatibility	Nonclinical testing and patient labeling
Induced astigmatism (which can result in blurred vision requiring glasses)	Labeling
Ptosis	Labeling

There are additional risks for the implantable eyelid weight, related to the more invasive position of the device, which include infection, device migration, and extrusion through the eyelid. In addition to special controls regarding biocompatibility testing and nonclinical testing for MR compatibility and labeling special controls, FDA is proposing special controls for the implantable eyelid weight addressing sterility and patient labeling. Biocompatibility testing will mitigate the risk of adverse tissue reaction, device migration, and extrusion through the eyelid. Sterility testing will mitigate the risk of infection. Nonclinical testing will mitigate the risk of MR incompatibility. Patient labeling will communicate potential MR incompatibility or the conditions for safe use in an MR environment. Labeling will mitigate the risk of adverse tissue reaction, device migration, extrusion through the eyelid, induced astigmatism, and ptosis.

FDA believes that the following special controls, in addition to general controls, will address the risks to health in table 2 of this document and provide reasonable assurance of safety and effectiveness of the implantable eyelid weight: (1) Testing demonstrating the biocompatibility of the device; (2) testing demonstrating the sterility and shelf life of the device; (3) nonclinical testing evaluating the compatibility of the device in an MR environment; and (4) patient labeling to convey information regarding the safety and compatibility of the device in

an MR environment, the conditions under which a patient with the device can be safely scanned, and a mechanism for a healthcare provider to obtain detailed information about MR safety and compatibility if needed. In addition, under § 801.109, the sale, distribution, and use of the device are restricted to prescription use.

III. Proposed Classification and FDA's Findings

To better inform the Agency's proposed classification of the eyelid weight device type as described in this proposed rule, FDA conducted a review of the literature that included relevant scientific and medical information published through 2011 (see representative articles in Refs. 2 through 20). FDA has received no reports of adverse events related to external or implantable eyelid weights. Based upon this updated review of the literature and FDA's continued premarket and postmarket experience with the device type, FDA agrees with the Panel's recommendation that the eyelid weight be classified into class II. FDA believes that special controls for both the external and implantable eyelid weight, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance. FDA also agrees with the Panel's recommendation that premarket notification is not necessary to assure the safety and effectiveness of the external eyelid weight and, therefore, the Agency is giving notice of intent to exempt the external eyelid weight device from premarket notification requirements.

IV. Proposed Effective Date

FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the Federal Register.

V. 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.

VI. Analysis of Impacts

A. Introduction

FDA has examined the impacts of the proposed 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 (Public Law 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 proposed rule is not a significant regulatory action as defined by 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 classifying these devices as class II will relieve manufacturers of external eyelid weights of the cost of complying with the premarket notification requirements of section 515 of the FD&C Act, and may permit small potential competitors to enter the marketplace by lowering costs, the Agency certifies that the proposed 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 \$139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Summary

The proposed rule would exempt manufacturers of external eyelid weights from submitting a premarket notification, provided they meet certain special controls. Manufacturers of implantable eyelid weights would still be required to submit a premarket notification and meet certain special controls. Because the proposed special controls are similar to those in place currently, we do not expect there to be any new costs to society. FDA has concluded that maintaining current controls will place no additional costs on producers and that meeting these special controls provides reasonable assurance that the devices are safe and effective. The special controls are not expected to pose new risks, and thus costs, to public health.

Adopting the proposed rule is expected to benefit society by removing the costs associated with preparing, reviewing, and responding to premarket notifications for manufacturers of external eyelid weights. We estimate the annual costs savings to be \$3,438. Over 20 years, the estimated present discounted value of the savings ranges from \$28,746, at a 3-percent discount rate, to \$20,470 at a 7-percent discount rate.

C. Preliminary Regulatory Impact Analysis

1. Benefits

Adopting the proposed rule would exempt manufacturers of external eyelid weights from submitting premarket notification, resulting in cost savings that are approximately equal to the expenses necessary to prepare, review, and respond to premarket notifications. To calculate these expenses, we multiply the average value of resources necessary to prepare, review, and respond to premarket notifications by the annual reduction in time spent working on these reports [= (the average cost to prepare, review, and respond to a premarket notification) * (annual reduction in number of premarket notifications for external eyelid weights)].

In the past decade, FDA has received one premarket notification related to external eyelid weights. The Agency expects this trend to remain relatively stable over time, and thus projects that implementing the proposed rule would result in an average annual reduction of 0.1 premarket notifications (= 1/10).

The average cost to prepare a premarket notification roughly equals the average number of pages per report multiplied by the average cost to prepare one page. FDA reviewers indicate that, in the last decade the average premarket notification on external eyelid weights is approximately 91 pages long. Blozan and Tucker (Ref. 21) indicates that it costs approximately \$500, on average, to prepare a premarket notification that is roughly 24 pages long. This estimate indicates that the average cost to prepare one page is \$21 (= \$500/24). Updated to 2011 dollars, per page costs roughly equal \$37.78 (Ref. 22). Given these measures, we estimate the average cost to prepare a premarket notification is approximately \$3,438 (= 91 * \$37.78).

The average cost to review one premarket notification was approximately \$13,400 in 2004 (Ref. 23). Updated to 2001 dollars, this cost roughly equals \$15,695 per premarket notification. Finally, most responses to premarket notifications are 5 pages long. Given that the

cost to prepare one page is roughly \$37.78, we estimate that the average cost to respond to a premarket notification roughly equals \$189 ($= 5 * \37.78).

2. Summary and Discussion

The proposed rule is expected to provide modest cost savings to society. We estimate that implementing the proposed rule is expected to result in an average annual cost savings equal to \$1932 ($= [0.1 \text{ reports per year}] * [\$3438 + \$15,695 + \$189]$). Over 20 years, the estimated present value of the savings is \$28,746, at a 3-percent discount rate, and \$20,470, at a 7-percent discount rate.

D. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires Agencies to prepare a regulatory flexibility analysis if a proposed rule would have a significant effect on a substantial number of small businesses, non-profit organizations, local jurisdictions, or other entities. The proposed rule would exempt manufacturers of external eyelid weights from submitting a premarket notification. We expect this exemption to modestly reduce costs associated with gaining premarket approval, and thus certify that the proposed rule would not significantly affect a substantial number of small businesses, non-profit organizations, local jurisdictions, or other entities.

VII. Paperwork Reduction Act of 1995

This proposed 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. 3501-3520). 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.

VIII. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IX. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified all the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Transcript from the Food and Drug Administration Ophthalmic Devices Panel Meeting, January 13 and 14, 2000.
2. Seiff, S. R., M. Boerner, and S. R. Carter, "Treatment of Facial Palsies With External Eyelid Weights," American Journal of Ophthalmology, vol. 120, no. 5, pp 652-657, November 1995.

3. Neuman, A. R., A. Weinberg, M. Sela, I. J. Peled, and M. R. Wexler, "The Correction of Seventh Nerve Palsy Lagophthalmos With Gold Lid Load (16 Years Experience)," Annals of Plastic Surgery, vol. 22, no. 2, pp. 142-145, February 1989.
4. Kelley, S. A. and D. T. Sharpe, "Gold Eyelid Weights in Patients With Facial Palsy: A Patient Review," Plastic and Reconstructive Surgery, vol. 89, no. 3, pp. 436-440, March 1992.
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9. Chapman, P. and B. G. Lamberty, "Results of Upper Lid Loading in the Treatment of Lagophthalmos Caused by Facial Palsy," British Journal of Plastic Surgery, vol. 41 no. 4, pp. 369-372, July 1988.
10. Seiff, S. R., J. H. Sullivan, L. N. Freeman, and J. Ahn, "Pretarsal Fixation of Gold Weights in Facial Nerve Palsy," Ophthalmic Plastic and Reconstructive Surgery, vol. 5, no. 2, pp. 104-109, 1989.

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15. Zwick, O. M. and S. R. Seiff, "Supportive Care of Facial Nerve Palsy with Temporary External Eyelid Weights," Optometry, vol. 77, no. 7, pp. 340-342, July 2006.
16. Williams, Z. R. and J. V. Aquavella, "Management of Exposure Keratopathy Associated with Severe Craniofacial Trauma," Journal of Cataract and Refractive Surgery, vol. 33, no. 9, pp. 1647-1650, September 2007.
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22. U.S. Department of Commerce, Bureau of Economic Analysis, National Income and Product Accounts Table 1.1.9 Implicit Price Deflators for Gross Domestic Product, <http://www.bea.gov/iTable/iTable.cfm?ReqID=9&step=1>, accessed January 17, 2013; National Income and Product Accounts Table 1.1.4 Price Indexes for Gross Domestic Product, <http://www.bea.gov/iTable/iTable.cfm?ReqID=9&step=1>, accessed January 17, 2013.
23. Geiger, D. R., "FY 2003 and 2004 Unit Costs for the Process of Medical Device Review," September 2005, <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109216.pdf>.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

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 886 be 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 886.5700 is added to subpart F to read as follows:

§ 886.5700 Eyelid weight.

(a) Identification. An eyelid weight is a prescription device made of gold, tantalum, platinum, iridium, or surgical grade stainless steel that is rectangular in shape and contoured to the shape of the eye. The device is intended for the gravity assisted treatment of lagophthalmos (incomplete eyelid closure).

(1) The external eyelid weight is adhered to the outer skin of the upper eyelid.

(2) The implantable eyelid weight is implanted into the upper eyelid.

(b) Classification. (1) Class II (special controls) for the external eyelid weight. The external eyelid weight is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9. The special controls for the external eyelid weight are:

(i) Testing demonstrating the biocompatibility of the device;

(ii) Nonclinical testing evaluating the compatibility of the device in a magnetic resonance (MR) environment;

(iii) Labeling to include all information required for the safe and effective use of the device as outlined in § 801.109(c) of this chapter, including specific instructions regarding the proper placement, sizing, and removal of the device; and

(2) Class II (special controls) for the implantable eyelid weight. The special controls for the implantable eyelid weight are:

(i) Testing demonstrating the biocompatibility of the device;

(ii) Testing demonstrating the sterility and shelf life of the device;

(iii) Nonclinical testing evaluating the compatibility of the device in an MR environment.

(iv) Patient labeling to convey information regarding the safety and compatibility of the device in an MR environment, the conditions under which a patient with the device can be safely scanned, and a mechanism for a healthcare provider to obtain detailed information about MR safety and compatibility if needed.

Dated: February 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-02862 Filed 02/07/2013 at 8:45 am; Publication Date: 02/08/2013]