

neither adulterated nor misbranded, and are marked as required by § 381.105.

PART 590—INSPECTION OF EGGS AND EGG PRODUCTS (EGG PRODUCTS INSPECTION ACT)

■ 14. The authority citation for part 590 continues to read as follows:

Authority: 21 U.S.C. 1031–1056.

■ 15. Add § 590.407 to read as follows:

§ 590.407 Export certification and marking of containers with export inspection mark.

(a) Exporters must apply for export certification of inspected and passed products shipped to any foreign country. Exporters may apply for an export certificate using a paper or electronic application. FSIS will assess exporters that submit an electronic application the charge in § 592.500(d) of this chapter.

(b) FSIS will issue only one certificate for each consignment, except in the case of error in the certificate or loss of the certificate originally issued. A request for a replacement certificate, except in the case of a lost certificate, must be accompanied by the original certificate. The new certificate will carry the following statement: “Issued in replacement of _____”, with the numbers of the certificates that have been superseded.

(c) FSIS will deliver a copy of the export certificate to the person who requested such certificate or his agent. Such persons may duplicate the certificate as required in connection with the exportation of the product.

(d) FSIS will retain a copy of the certificate.

(e)(1) When authorized by inspection personnel, establishments must mark the outside container of any inspected and passed egg products destined for export, the securely enclosed pallet within the consignment, or closed means of conveyance transporting the consignment, with a mark that contains a unique identifier that links the consignment to the export certificate or an official mark with the following form:¹



(2) Ship stores, small quantities exclusively for the personal use of the consignee and not for sale or

¹ The number “1234567” is given as an example only. The number on the export certificate will correspond to the printed number on the export certificate.

distribution, and shipments by and for the U.S. Armed Forces, are exempt from the requirements of this section.

(f) Exporters may request inspection personnel to issue certificates for export consignments of product of official establishments not under their supervision, provided the consignments are first identified as having been “U.S. inspected and passed,” are found to be neither adulterated nor misbranded, and are marked as required by paragraph (e) of this section.

PART 592—VOLUNTARY INSPECTION OF EGG PRODUCTS

■ 16. The authority citation for part 592 continues to read as follows:

Authority: 7 U.S.C. 1621–1627.

■ 17. In § 592.20, add paragraph (d) to read as follows:

§ 592.20 Kinds of services available.

* * * * *

(d) *Export certification.* Upon application, by any person intending to export any egg product, inspectors may make certifications regarding products for human food purposes, to be exported, as meeting conditions or standards that are not imposed or are in addition to those imposed by the regulations in the part and the laws under which such regulations were issued.

■ 18. In § 592.500, revise paragraph (a) and add paragraphs (d), (e), and (f) to read as follows:

§ 592.500 Payment of fees and charges.

(a) Fees and charges for voluntary base time rate, overtime inspection service, holiday inspection service, and electronic export applications shall be paid by the interested party making the application for such service, in accordance with the applicable provisions of this section and § 592.510 through § 592.530, both inclusive. If so required by the inspection personnel, such fees and charges shall be paid in advance.

* * * * *

(d) Exporters that submit electronic export certificate applications will be charged a fee per application submitted.

(e) For each calendar year, FSIS will calculate the electronic export certificate application fee, using the following formula: Labor Costs (Technical Support Cost + Export Library Maintenance Cost) + Information Technology Costs (On-going operations Cost + Maintenance Cost + eAuthentication Cost), divided by the number of export applications.

(f) FSIS will publish notice of the electronic export certificate application fee annually in the **Federal Register**.

Done at Washington, DC, on June 17, 2016.
Alfred V. Almanza,
Acting Administrator.

[FR Doc. 2016–14812 Filed 6–28–16; 8:45 am]
BILLING CODE 3410–DM–P

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[Docket No. EERE–2014–BT–TP–0044]

RIN 1904–AD45

Energy Conservation Program: Test Procedure for Battery Chargers

Correction

In rule document 2016–11486, beginning on page 31827 in the issue of Friday, May 20, 2016, make the following corrections:

Appendix Y to Subpart B of Part 430 [Corrected]

1. On page 31844, in Appendix Y to Subpart B of Part 430, in Table 5.3, under the “Product Class” column head, in the “Rated Battery Energy (Ebatt)” ** column, in the third row, the entry should read “<100 Wh”.

2. On the same page, in the same table, beneath the same column head, in the same column, in the fourth row, the entry should read “<100 Wh”.

3. On the same page, in the same table, beneath the same column head, in the same column, in the sixth row, the entry should read “100–3000 Wh”.

[FR Doc. C1–2016–11486 Filed 6–28–16; 8:45 am]
BILLING CODE 1505–05–D

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 308 and 327

RIN 3064–AE43

Rules of Practice and Procedure

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Interim final rule and request for comment.

SUMMARY: The Federal Deposit Insurance Corporation (FDIC) is amending its rules of practice and procedure under to adjust the maximum amount of each civil money penalty (CMP) within its jurisdiction to account for inflation. This action is required by the Federal Civil Penalties Inflation

Adjustment Act Improvements Act of 2015 (2015 Adjustment Act).

DATES: This rule is effective on August 1, 2016. Comments must be received by September 1, 2016.

ADDRESSES: You may submit comments, identified by RIN 3064–AE43, by any of the following methods:

- *Agency Web site:* <http://www.fdic.gov/regulations/laws/federal/>. Follow instructions for submitting comments on the Agency Web site.

- *Email:* Comments@fdic.gov. Include the RIN 3064–AE43 on the subject line of the message.

- *Mail:* Robert E. Feldman, Executive Secretary, Attention: Comments, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 550 17th Street Building (located on F Street) on business days between 7:00 a.m. and 5:00 p.m.

Public Inspection: All comments received must include the agency name and RIN for this rulemaking. All comments received will be posted without change to <http://www.fdic.gov/regulations/laws/federal/>, including any personal information provided. Paper copies of public comments may be ordered from the FDIC Public Information Center, 3501 North Fairfax Drive, Room E–1002, Arlington, VA 22226 by telephone at (877) 275–3342 or (703) 562–2200.

FOR FURTHER INFORMATION CONTACT: Seth P. Rosebrock, Supervisory Counsel, Legal Division (202) 898–6609, or Graham N. Rehrig, Senior Attorney, Legal Division (202) 898–3829.

SUPPLEMENTARY INFORMATION:

I. Policy Objectives

This interim final rule adjusts the maximum limit for CMPs according to inflation as mandated by Congress in the 2015 Adjustment Act.¹ The intended effect of annually adjusting maximum civil money penalties in accordance with changes in the Consumer Price Index is to minimize any distortion in the real value of those maximums due to inflation, thereby promoting a more consistent deterrent effect in the structure of CMPs. Other technical changes to 12 CFR part 308 are intended to improve the transparency of the regulation and to assist readers in quickly identifying the applicable CMP amounts.

II. Background: Current Regulatory Approach

The FDIC assesses CMPs under section 8(i) of the Federal Deposit

Insurance Act (FDIA), 12 U.S.C. 1818, and a variety of other statutes.² Congress established maximum penalties that could be assessed under these statutes. In many cases, these statutes contain multiple penalty tiers, permitting the assessment of penalties at various levels depending upon the severity of the misconduct at issue.³

In 1990, Congress determined that the assessment of CMPs plays “an important role in deterring violations and furthering the policy goals embodied in such laws and regulations” and concluded that “the impact of many civil monetary penalties has been and is diminished due to the effect of inflation.”⁴ Consequently, Congress required federal agencies with authority to impose CMPs to periodically adjust by rulemaking the maximum CMPs which these agencies were authorized to impose in order to “maintain the deterrent effect of civil monetary penalties and promote compliance with the law.”⁵ Under the 1990 Adjustment Act, the FDIC adjusted its CMP amounts every four years, most recently in 2012.⁶

In 2015, Congress revised the process by which federal agencies adjust applicable CMPs for inflation.⁷ Under the 2015 Adjustment Act, the FDIC is required to (1) adjust the CMP levels with an initial catch-up adjustment through an interim final rulemaking and (2) make subsequent annual adjustments for inflation. The FDIC must publish an interim final rule with initial penalty adjustment amounts by July 1, 2016, and the new maximum penalty levels must take effect no later than August 1, 2016. These adjustments will apply to all CMPs covered by the 2015 Adjustment Act.⁸

² See, e.g., 12 U.S.C. 1972(2)(F) (authorizing the FDIC to impose CMPs for violations of the Bank Holding Company Act of 1970 related to prohibited tying arrangements); 15 U.S.C. 78u–2 (authorizing the FDIC to impose CMPs for violations of certain provisions of the Securities Exchange Act of 1934); 42 U.S.C. 4012a(f) (authorizing the FDIC to impose CMPs for pattern or practice violations of the Flood Disaster Protection Act).

³ For example, Section 8(i)(2) of the FDIA, 12 U.S.C. 1818(i)(2), provides for three tiers of CMPs, with the size of such CMPs increasing with the gravity of the misconduct.

⁴ Section 2 of the Federal Civil Penalties Inflation Adjustment Act of 1990 (1990 Adjustment Act). Public Law 101–410, 104 Stat. 890 (amended 2015) (codified as amended at 28 U.S.C. 2461 note).

⁵ *Id.*

⁶ See 77 FR 74,573 (Dec. 17, 2012).

⁷ Public Law 114–74, 129 Stat. 584.

⁸ The 2015 Adjustment Act defines “civil monetary penalty” as “any penalty, fine, or other sanction that is for a specific monetary amount as provided by Federal law; or has a maximum amount provided for by Federal law; and is assessed or enforced by an agency pursuant to Federal law; and is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts[.]” Public Law 101–410, sec. 3(2),

Although the 2015 Adjustment Act increases the maximum penalty that may be assessed under each applicable statute, the FDIC possesses discretion to impose CMP amounts below the maximum level in accordance with the severity of the misconduct at issue. When making a determination as to the appropriate level of any given penalty, the FDIC is guided by statutory factors set forth in section 8(i)(2)(G) of the FDIA, 12 U.S.C. 1818(i)(2)(G), and those factors identified in the *Interagency Policy Statement Regarding the Assessment of CMPs by the Federal Financial Institutions Regulatory Agencies*.⁹ Such factors include, but are not limited to, the gravity and duration of the misconduct, and the intent related to the misconduct.

III. Description of the Rule

This interim final rule adjusts the maximum limit for CMPs according to inflation as mandated by Congress in the 2015 Adjustment Act. Additionally, other technical changes to 12 CFR part 308 are being made to correct typographical errors, to supplement 12 CFR 308.132 to include references to previously omitted CMPs, and to reorder the provisions of 12 CFR 308.132 to assist readers in quickly identifying applicable CMP amounts.

The New CMP-Adjustment System

The 2015 Adjustment Act directs federal agencies to follow guidance issued by the Office of Management and Budget (OMB) on February 24, 2016 (OMB Guidance) when calculating new maximum penalty levels.¹⁰ Initial catch-up adjustments are to be based on the percent change between the Consumer Price Index for all Urban Consumers (CPI-U)¹¹ for the month of October in the year for which the CMP was established by Congress or last adjusted for inflation (other than through the 1990 Adjustment Act), and the October 2015 CPI-U.¹² In addition, the OMB

104 Stat. 890 (amended 2015) (codified as amended at 28 U.S.C. 2461 note).

⁹ 63 FR 30227 (June 3, 1998).

¹⁰ See OMB, Implementation of the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, M–16–06 available at <https://www.whitehouse.gov/sites/default/files/omb/memoranda/2016/m-16-06.pdf>.

¹¹ The CPI-U is compiled by the Bureau of Statistics of the Department of Labor.

¹² The OMB Guidance directs agencies to identify, for each CMP, the year and corresponding amount(s) for which the maximum penalty level or range of minimum and maximum penalties was established (*i.e.*, as originally enacted by Congress), or last adjusted (*i.e.*, by Congress in statute, or by the agency through regulation), whichever is later, other than under the Inflation Adjustment Act. OMB Guidance at 3.

¹ Public Law 114–74, sec. 701, 129 Stat. 584.

Guidance provides a table of CMP-adjustment multipliers for each year.¹³

Summary of the FDIC's Calculations

In keeping with the OMB Guidance, the FDIC multiplied each of its CMP amounts by the relevant inflation factor.¹⁴ After applying the multiplier, the FDIC rounded each penalty level to the nearest dollar. In accordance with the 2015 Adjustment Act, the FDIC did not increase penalty levels by more than 150 percent of the corresponding levels

in effect on November 2, 2015. In making these calculations, the FDIC consulted with staff from the Office of the Comptroller of the Currency, the Board of Governors for the Federal Reserve System, the National Credit Union Administration, and the Bureau of Consumer Financial Protection to ensure that the FDIC's calculations and adjustments are consistent with those being proposed by other federal

financial regulators for the same statutes.

Summary of Adjustments

The following chart displays the adjusted CMP amounts for each CMP identified in 12 CFR part 308.¹⁵ The following chart reflects the maximum CMPs that may be assessed through July 31, 2016, and the maximum CMPs that may be assessed on or after August 1, 2016, after the required inflation adjustment:

U.S. Code citation	Current maximum CMP (through July 31, 2016)	Adjusted maximum CMP (beginning August 1, 2016)
12 U.S.C. 1464(v):		
Tier One CMP	\$3,200	\$3,787
Tier Two CMP	32,000	37,872
Tier Three CMP	1,425,000	1,893,610
12 U.S.C. 1467(d)	7,500	9,468
12 U.S.C. 1817(a):		
Tier One CMP	3,200	3,787
Tier Two CMP	32,000	37,872
Tier Three CMP	1,425,000	1,893,610
12 U.S.C. 1817(c):		
Tier One CMP	3,200	3,462
Tier Two CMP	32,000	34,620
Tier Three CMP	1,425,000	1,730,990
12 U.S.C. 1818(i)(2):		
Tier One CMP	7,500	9,468
Tier Two CMP	37,500	47,340
Tier Three CMP	1,425,000	1,893,610
12 U.S.C. 1820(e)(4)	7,500	8,655
12 U.S.C. 1820(k)(6)	275,000	311,470
12 U.S.C. 1828(a)(3)	100	118
12 U.S.C. 1828(h):		
For assessments <\$10,000	100	118
12 U.S.C. 1829b(j)	16,000	19,787
12 U.S.C. 1832(c)	1,100	2,750
12 U.S.C. 1884	110	275
12 U.S.C. 1972(2)(F):		
Tier One CMP	7,500	9,468
Tier Two CMP	37,500	47,340
Tier Three CMP	1,425,000	1,893,610
12 U.S.C. 3909(d)	1,100	2,355
15 U.S.C. 78u-2:		
Tier One CMP (individuals)	7,500	8,908
Tier One CMP (others)	70,000	89,078
Tier Two CMP (individuals)	70,000	89,078
Tier Two CMP (others)	350,000	445,390
Tier Three CMP (individuals)	140,000	178,156
Tier Three penalty (others)	700,000	890,780
15 U.S.C. 1639e(k):		
First violation	10,000	10,875
Subsequent violations	20,000	21,749
31 U.S.C. 3802	7,500	10,781
42 U.S.C. 4012a(f)	2,000	2,056

CFR Citation	Current maximum amount (through July 31, 2016)	New maximum amount (beginning August 1, 2016)
12 CFR 308.132(c)—Late or Misleading Reports of Condition and Income (Call Reports)		
<i>First Offense:</i>		
\$25 million or more assets:		
1 to 15 days late	\$330	\$519
16 or more days late	660	1,039
Less than \$25 million assets:		

¹³ OMB Guidance at 6.
¹⁴ Under the 1990 Adjustment Act, adjustments have been made only to CMPs that are for specific

dollar amounts or maximums. CMPs that are assessed based upon a fixed percentage of an institution's total assets are not subject to adjustment.

¹⁵ As noted previously, the FDIC retains discretion to impose CMPs in amounts below the referenced maximums.

CFR Citation	Current maximum amount (through July 31, 2016)	New maximum amount (beginning August 1, 2016)
1 to 15 days late	110	173
16 or more days late	220	346
<i>Subsequent Offenses</i>		
\$25 million or more assets:		
1 to 15 days late	550	865
16 or more days late	1,100	1,731

Addition to Part 308 of CMPs Previously Omitted

This interim final rule incorporates adjustments to two categories of CMPs previously inadvertently omitted from the FDIC’s last inflation-adjustment rulemaking in 2012. The Dodd-Frank Act¹⁶ amended the Truth in Lending Act to establish independence standards for property appraisals and authorized the FDIC and other federal agencies to assess specified CMPs against persons who violate these provisions (Appraisal Independence CMP).¹⁷ Title III of the Dodd-Frank Act also transferred the functions, powers, and duties of the Office of Thrift Supervision relating to State savings associations to the FDIC and amended section 3 of the Federal Deposit Insurance Act to designate the FDIC as the “appropriate Federal banking agency” for State savings associations. Among the transferred authorities was the authority to impose CMPs against any State savings association under section 9(d) of the Home Owners’ Loan Act (HOLA) (12 U.S.C. 1467(d)) if an affiliate of such an institution refuses to permit a duly-appointed examiner to conduct an examination or refuses to provide information during the course of an examination (Savings Association CMP).

Neither the Appraisal Independence CMP nor the Savings Association CMP was previously included in part 308. Nonetheless, the FDIC is required by the 2015 Adjustment Act to adjust all CMPs under the FDIC’s jurisdiction in the agency’s inflation-adjustment rulemaking. Consequently, the present amendment to part 308 specifically incorporates provisions in 12 CFR 308.132 related to the Appraisal Independence CMP and Savings Association CMP in 12 CFR 308.132, applying the adjustments required under the 2015 Adjustment Act and the OMB Guidance to these penalties.

Other Technical Changes to 12 CFR Part 308

The FDIC corrected a typographical error in 12 CFR 308.132(c) by indicating

that the FDIC’s Board of Directors or its designee may assess CMPs under 12 CFR 308.1(e) rather than the incorrect “308.01(e)(1).”

The FDIC reorganized 12 CFR 308.132, listing all statutes cited that give rise to CMPs in ascending alpha-numeric order by title and section to assist readers in quickly identifying the applicable CMP amounts.

Finally, the FDIC revised existing cross-references to 12 CFR 308.132 that are found in Chapter III of Title 12 of the Code of Federal Regulations to reflect the resultant reorganization of 12 CFR 308.132.

IV. Expected Effects of the Rule

The interim final rule is expected to more precisely adjust CMP maximums relative to inflation. These adjustments are expected to minimize any year-to-year distortions in the real value of the CMP maximums. These adjustments will promote a more consistent deterrent effect in the structure of CMPs. As previously noted, the FDIC retains discretion to impose CMP amounts below the maximum level. The actual number and size of CMPs assessed in the future will depend on the propensity and severity of the violations committed by banks and institution-affiliated parties, as well as the particular statute that is at issue. Such future violations cannot be reliably forecast. It is expected that the FDIC will continue to exercise its discretion to impose CMPs that are appropriate to their severity.

The 2015 Adjustment Act will likely result in a minimal increase in administrative costs for the FDIC in order to establish new inflation-adjusted maximum CMPs each year. Because these calculations are relatively simple, the number of labor hours necessary to perform this task is likely to be insignificant relative to total enforcement labor hours for the Corporation.

V. Alternatives Considered

The 2015 Act mandates the frequency of the inflation adjustment and the measure of inflation to be used in making these adjustments; accordingly, the FDIC is not statutorily authorized to

consider or pursue alternative approaches. The other technical changes to 12 CFR part 308 were relatively minor and designed to improve the transparency and readability of the CFR, and therefore the FDIC did not actively consider alternative approaches to these changes.

VI. Request for Comment

The 2015 Adjustment Act requires the FDIC to amend its rules through an interim final rulemaking and provides the specific adjustments to be made. These changes are ministerial and technical. Under the OMB Guidance, the FDIC is not required to complete a notice-and-comment process prior to publication of this interim final rule in the **Federal Register**.¹⁸ Nonetheless, although notice and comment rulemaking procedures are not required, the FDIC invites comments on all aspects of this interim final rule. Commenters are specifically encouraged to identify any technical issues raised by the rule, including identifying any potential CMPs that may have been unintentionally omitted from this adjustment rulemaking.

VII. Regulatory Analysis

Riegle Community Development and Regulatory Improvement Act

Section 302 of the Riegle Community Development and Regulatory Improvement Act¹⁹ generally requires that regulations prescribed by federal banking agencies which impose additional reporting, disclosures, or other new requirements on insured depository institutions take effect on the first day of a calendar quarter unless the regulation is required to take effect on another date pursuant to another act of Congress or the agency determines for good cause that the regulation should become effective on an earlier date.

This interim final rule merely adjusts the maximum CMPs which the FDIC may assess. It does not impose any new or additional reporting, disclosures, or other requirements on insured depository institutions. Additionally, as previously noted, the 2015 Adjustment

¹⁶ Public Law 111–203, tit. XIV, sec. 1472(a), 124 Stat. 2187.

¹⁷ 15 U.S.C. 1639e(k).

¹⁸ OMB Guidance at 3.

¹⁹ 12 U.S.C. 4802.

Act requires the interim final rule to take effect no later than August 1, 2016.²⁰ Accordingly, this interim final rule will be effective August 1, 2016.

Regulatory Flexibility Act

An initial regulatory flexibility analysis under the Regulatory Flexibility Act²¹ (RFA) is required only when an agency must publish a general notice of proposed rulemaking. As noted above, the FDIC determined that publication of a notice of proposed rulemaking is not necessary for this interim final rule. Accordingly, the RFA does not require an initial regulatory flexibility analysis. Nevertheless, the FDIC considered the likely impact of the rule on small entities. From 2011 through 2015, on average, only 1.6 percent of FDIC-supervised institutions were ordered to pay a CMP each year. Accordingly, the FDIC believes that the rule will not have a significant impact on a substantial number of small entities.

Small Business Regulatory Enforcement Fairness Act

The OMB has determined that the interim final rule is not a “major rule” within the meaning of the relevant sections of the Small Business Regulatory Enforcement Act of 1996 (SBREFA).²² As required by SBREFA, the FDIC will submit the interim final rule and other appropriate reports to Congress and the Government Accountability Office for review.

The Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999: Assessment of Federal Regulations and Policies on Families

The FDIC determined that this final rule will not affect family wellbeing within the meaning of section 654 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999.²³

Paperwork Reduction Act

The interim rule will implement statutory changes to the FDIC’s CMP regulations. It does not create any new, or revise any existing, collections of information under section 3504(h) of the Paperwork Reduction Act of 1980.²⁴ Consequently, no information collection request will be submitted to the OMB for review.

Plain Language Act

Section 722 of the Gramm-Leach-Bliley Act requires the FDIC to use plain language in all proposed and final rules published after January 1, 2000.²⁵ The FDIC invites comment on how to make this rule easier to understand. For example:

- Has the FDIC organized the material to suit your needs? If not, how could the FDIC present the rule more clearly?
- Are the requirements in the rule clearly stated? If not, how could the rule be more clearly stated?
- Do the regulations contain technical language or jargon that is not clear? If so, which language requires clarification?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the regulation easier to understand? If so, what changes would achieve that?
- Is this section format adequate? If not, which of the sections should be changed and how?
- What other changes can the FDIC incorporate to make the regulation easier to understand?

List of Subjects

12 CFR Part 308

Administrative practice and procedure, Banks, banking, Claims, Crime, Equal access to justice, Ex parte communications, Hearing procedure, Lawyers, Penalties, State nonmember banks.

12 CFR Part 327

Bank deposit insurance, Banks, banking, Savings associations.

For the reasons set forth in the preamble, the FDIC amends 12 CFR parts 308 and 327 to read as follows:

PART 308—RULES OF PRACTICE AND PROCEDURE

- 1. Revise the authority citation for 12 CFR part 308 to read as follows:

Authority: 5 U.S.C. 504, 554–557; 12 U.S.C. 93(b), 164, 505, 1464, 1467(d), 1467a, 1468, 1815(e), 1817, 1818, 1819, 1820, 1828, 1829, 1829(b), 1831i, 1831m(g)(4), 1831o, 1831p–1, 1832(c), 1884(b), 1972, 3102, 3108(a), 3349, 3909, 4717, 5412(b)(2)(C), 5414(b)(3); 15 U.S.C. 78(h) and (i), 78o(c)(4), 78o–4(c), 78o–5, 78q–1, 78s, 78u, 78u–2, 78u–3, 78w, 6801(b), 6805(b)(1); 28 U.S.C. 2461 note; 31 U.S.C. 330, 5321; 42 U.S.C. 4012a; Pub. L. 104–134, sec. 31001(s), 110 Stat. 1321; Pub. L. 109–351, 120 Stat. 1966; Pub. L. 111–203, 124 Stat. 1376; Pub. L. 114–74, sec. 701, 129 Stat. 584.

- 2. Revise § 308.116(b)(4) to read as follows:

§ 308.116 Assessment of penalties.

* * * * *

(b) * * * * *
(4) *Adjustment of civil money penalties by the rate of inflation pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.* On or after August 1, 2016:

(i) Any person who has engaged in a violation as set forth in paragraph (b)(1) of this section shall forfeit and pay a civil money penalty of not more than \$9,468 for each day the violation continued.

(ii) Any person who has engaged in a violation, unsafe or unsound practice or breach of fiduciary duty, as set forth in paragraph (b)(2) of this section, shall forfeit and pay a civil money penalty of not more than \$47,340 for each day such violation, practice or breach continued.

(iii) Any person who has knowingly engaged in a violation, unsafe or unsound practice or breach of fiduciary duty, as set forth in paragraph (b)(3) of this section, shall forfeit and pay a civil money penalty not to exceed:

(A) In the case of a person other than a depository institution—\$1,893,610 per day for each day the violation, practice or breach continued; or

(B) In the case of a depository institution—an amount not to exceed the lesser of \$1,893,610 or one percent of the total assets of such institution for each day the violation, practice or breach continued.

* * * * *

- 3. Amend § 308.132 by revising paragraph (c)(1) and adding paragraph (d) to read as follows:

§ 308.132 Assessment of penalties.

* * * * *

(c)
(1) *Authority of the Board of Directors.* The Board of Directors or its designee may assess civil money penalties pursuant to section 8(i) of the FDIA (12 U.S.C. 1818(i)), and § 308.1(e) of the Uniform Rules (this part).

* * * * *

(d) *Maximum civil money penalty amounts.* Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, on or after August 1, 2016, the Board of Directors or its designee may assess civil money penalties in the maximum amounts as follows:

(1) *Civil money penalties assessed pursuant to 12 U.S.C. 1464(v) for late filing or the submission of false or misleading certified statements by State savings associations.* Pursuant to section 5(v) of the Home Owners’ Loan Act (12 U.S.C. 1464(v)), the Board of Directors or its designee may assess civil money penalties as follows:

²⁰ Public Law 114–74, 129 Stat. 584.

²¹ 5 U.S.C. 603.

²² 5 U.S.C. 801 *et seq.*

²³ Public Law 105–277, 112 Stat. 2681 (1998).

²⁴ 44 U.S.C. 3501 *et seq.*

²⁵ Public Law 106–102, 113 Stat. 1338 (Nov. 12, 1999).

(i) *Late filing—Tier One penalties.* In cases in which an institution fails to make or publish its Report of Condition and Income (Call Report) within the appropriate time periods, a civil money penalty of not more than \$3,787 per day may be assessed where the institution maintains procedures in place reasonably adapted to avoid inadvertent error and the late filing occurred unintentionally and as a result of such error; or the institution inadvertently transmitted a Call Report that is minimally late. For penalties assessed on or after August 1, 2016, for violations of this paragraph (d)(1)(i), the following maximum Tier One penalty amounts contained in paragraphs (d)(1)(i)(A) and (B) of this section shall apply for each day that the violation continues.

(A) *First offense.* Generally, in such cases, the amount assessed shall be \$519 per day for each of the first 15 days for which the failure continues, and \$1,039 per day for each subsequent day the failure continues, beginning on the sixteenth day. For institutions with less than \$25,000,000 in assets, the amount assessed shall be the greater of \$173 per day or 1/1000th of the institution's total assets (1/10th of a basis point) for each of the first 15 days for which the failure continues, and \$346 or 1/500th of the institution's total assets, 1/5 of a basis point) for each subsequent day the failure continues, beginning on the sixteenth day.

(B) *Subsequent offense.* Where the institution has been delinquent in making or publishing its Call Report within the preceding five quarters, the amount assessed for the most current failure shall generally be \$865 per day for each of the first 15 days for which the failure continues, and \$1,731 per day for each subsequent day the failure continues, beginning on the sixteenth day. For institutions with less than \$25,000,000 in assets, those amounts, respectively, shall be 1/500th of the bank's total assets and 1/250th of the institution's total assets.

(C) *Lengthy or repeated violations.* The amounts set forth in this paragraph (d)(1)(i) will be assessed on a case by case basis where the amount of time of the institution's delinquency is lengthy or the institution has been delinquent repeatedly in making or publishing its Call Reports.

(D) *Waiver.* Absent extraordinary circumstances outside the control of the institution, penalties assessed for late filing shall not be waived.

(ii) *Late-filing—Tier Two penalties.* Where an institution fails to make or publish its Call Report within the appropriate time period, the Board of Directors or its designee may assess a

civil money penalty of not more than \$37,872 per day for each day the failure continues.

(iii) *False or misleading reports or information—(A) Tier One penalties.* In cases in which an institution submits or publishes any false or misleading Call Report or information, the Board of Directors or its designee may assess a civil money penalty of not more than \$3,787 per day for each day the information is not corrected, where the institution maintains procedures in place reasonably adapted to avoid inadvertent error and the violation occurred unintentionally and as a result of such error; or the institution inadvertently transmits a Call Report or information that is false or misleading.

(B) *Tier Two penalties.* Where an institution submits or publishes any false or misleading Call Report or other information, the Board of Directors or its designee may assess a civil money penalty of not more than \$37,872 per day for each day the information is not corrected.

(C) *Tier Three penalties.* Where an institution knowingly or with reckless disregard for the accuracy of any Call Report or information submits or publishes any false or misleading Call Report or other information, the Board of Directors or its designee may assess a civil money penalty of not more than the lesser of \$1,893,610 or 1 percent of the institution's total assets per day for each day the information is not corrected.

(iv) *Mitigating factors.* The amounts set forth in this paragraph (d)(1) may be reduced based upon the factors set forth in paragraph (b) of this section.

(2) *Civil money penalties assessed pursuant to 12 U.S.C. 1467(d) for refusal by an affiliate of a State savings association to allow examination or to provide required information during an examination.* Pursuant to section 9(d) of the Home Owners' Loan Act (12 U.S.C. 1467(d)), civil money penalties may be assessed against any State savings association if an affiliate of such an institution refuses to permit a duly-appointed examiner to conduct an examination or refuses to provide information during the course of an examination as set forth 12 U.S.C. 1467(d), in an amount not to exceed \$9,486 for each day the refusal continues.

(3) *Civil money penalties assessed pursuant to 12 U.S.C. 1817(a) for late filings or the submission of false or misleading reports of condition.* Pursuant to section 7(a) of the FDIA (12 U.S.C. 1817(a)), the Board of Directors or its designee may assess civil money penalties as follows:

(i) *Late filing—Tier One penalties.* In cases in which an institution fails to make or publish its Report of Condition and Income (Call Report) within the appropriate time periods, a civil money penalty of not more than \$3,787 per day may be assessed where the institution maintains procedures in place reasonably adapted to avoid inadvertent error and the late filing occurred unintentionally and as a result of such error; or the institution inadvertently transmitted a Call Report that is minimally late. For penalties assessed on or after August 1, 2016, for violations of this paragraph (d)(3)(i), the following maximum Tier One penalty amounts contained in paragraphs (d)(3)(i)(A) and (B) of this section shall apply for each day that the violation continues.

(A) *First offense.* Generally, in such cases, the amount assessed shall be \$519 per day for each of the first 15 days for which the failure continues, and \$1,039 per day for each subsequent day the failure continues, beginning on the sixteenth day. For institutions with less than \$25,000,000 in assets, the amount assessed shall be the greater of \$173 per day or 1/1000th of the institution's total assets (1/10th of a basis point) for each of the first 15 days for which the failure continues, and \$346 or 1/500th of the institution's total assets, 1/5 of a basis point) for each subsequent day the failure continues, beginning on the sixteenth day.

(B) *Subsequent offense.* Where the institution has been delinquent in making or publishing its Call Report within the preceding five quarters, the amount assessed for the most current failure shall generally be \$865 per day for each of the first 15 days for which the failure continues, and \$1,731 per day for each subsequent day the failure continues, beginning on the sixteenth day. For institutions with less than \$25,000,000 in assets, those amounts, respectively, shall be 1/500th of the bank's total assets and 1/250th of the institution's total assets.

(C) *Lengthy or repeated violations.* The amounts set forth in this paragraph (d)(3)(i) will be assessed on a case by case basis where the amount of time of the institution's delinquency is lengthy or the institution has been delinquent repeatedly in making or publishing its Call Reports.

(D) *Waiver.* Absent extraordinary circumstances outside the control of the institution, penalties assessed for late filing shall not be waived.

(ii) *Late-filing—Tier Two penalties.* Where an institution fails to make or publish its Call Report within the appropriate time period, the Board of Directors or its designee may assess a

civil money penalty of not more than \$34,620 per day for each day the failure continues.

(iii) *False or misleading reports or information*—(A) *Tier One penalties*. In cases in which an institution submits or publishes any false or misleading Call Report or information, the Board of Directors or its designee may assess a civil money penalty of not more than \$3,787 per day for each day the information is not corrected, where the institution maintains procedures in place reasonably adapted to avoid inadvertent error and the violation occurred unintentionally and as a result of such error; or the institution inadvertently transmits a Call Report or information that is false or misleading.

(B) *Tier Two penalties*. Where an institution submits or publishes any false or misleading Call Report or other information, the Board of Directors or its designee may assess a civil money penalty of not more than \$37,872 per day for each day the information is not corrected.

(C) *Tier Three penalties*. Where an institution knowingly or with reckless disregard for the accuracy of any Call Report or information submits or publishes any false or misleading Call Report or other information, the Board of Directors or its designee may assess a civil money penalty of not more than the lesser of \$1,893,610 or 1 percent of the institution's total assets per day for each day the information is not corrected.

(iv) *Mitigating factors*. The amounts set forth in this paragraph (d)(3) may be reduced based upon the factors set forth in paragraph (b) of this section.

(4) *Civil money penalties assessed pursuant to 12 U.S.C. 1817(c) for late filing or the submission of false or misleading certified statements*. Tier One civil money penalties may be assessed pursuant to section 7(c)(4)(A) of the FDIA (12 U.S.C. 1817(c)(4)(A)) in an amount not to exceed \$3,462 for each day during which the failure to file continues or the false or misleading information is not corrected. Tier Two civil money penalties may be assessed pursuant to section 7(c)(4)(B) of the FDIA (12 U.S.C. 1817(c)(4)(B)) in an amount not to exceed \$34,620 for each day during which the failure to file continues or the false or misleading information is not corrected. Tier Three civil money penalties may be assessed pursuant to section 7(c)(4)(C) in an amount not to exceed the lesser of \$1,730,990 or 1 percent of the total assets of the institution for each day during which the failure to file continues or the false or misleading information is not corrected.

(5) *Civil money penalties assessed pursuant to section 8(i)(2) of the FDIA*. Tier One civil money penalties may be assessed pursuant to section 8(i)(2)(A) of the FDIA (12 U.S.C. 1818(i)(2)(A)) in an amount not to exceed \$9,468 for each day during which the violation continues. Tier Two civil money penalties may be assessed pursuant to section 8(i)(2)(B) of the FDIA (12 U.S.C. 1818(i)(2)(B)) in an amount not to exceed \$47,340 for each day during which the violation, practice or breach continues. Tier Three civil money penalties may be assessed pursuant to section 8(i)(2)(C) (12 U.S.C. 1818(i)(2)(C)) in an amount not to exceed, in the case of any person other than an insured depository institution \$1,893,610 or, in the case of any insured depository institution, an amount not to exceed the lesser of \$1,893,610 or 1 percent of the total assets of such institution for each day during which the violation, practice, or breach continues.

(i) Pursuant to 7(j)(16) of the FDIA (12 U.S.C. 1817(j)(16)), a civil money penalty may be assessed for violations of change in control of insured depository institution provisions pursuant to section 8(i)(2) of the FDIA (12 U.S.C. 1818(i)(2)) in the amounts set forth in paragraph (d)(5) of this section.

(ii) Pursuant to the International Banking Act of 1978 (IBA) (12 U.S.C. 3108(b)), civil money penalties may be assessed for failure to comply with the requirements of the IBA pursuant to section 8(i)(2) of the FDIA (12 U.S.C. 1818(i)(2)), in the amounts set forth in paragraph (d)(5).

(iii) Pursuant to section 1120(b) of the Financial Institutions Recovery, Reform, and Enforcement Act of 1989 (FIRREA) (12 U.S.C. 3349(b)), where a financial institution seeks, obtains, or gives any other thing of value in exchange for the performance of an appraisal by a person that the institution knows is not a state certified or licensed appraiser in connection with a federally related transaction, a civil money penalty may be assessed pursuant to section 8(i)(2) of the FDIA (12 U.S.C. 1818(i)(2)) in the amounts set forth in paragraph (d)(5) of this section.

(iv) Pursuant to the Community Development Banking and Financial Institution Act (Community Development Banking Act) (12 U.S.C. 4717(b)) a civil money penalty may be assessed for violations of the Community Development Banking Act pursuant to section 8(i)(2) of the FDIA (12 U.S.C. 1818(i)(2)), in the amount set forth in paragraph (d)(5) of this section.

(v) Civil money penalties may be assessed pursuant to section 8(i)(2) of

the FDIA in the amounts set forth in this paragraph (d)(5) for violations of various consumer laws, including, but not limited to, the Home Mortgage Disclosure Act (12 U.S.C. 2804 *et seq.* and 12 CFR 203.6), the Expedited Funds Availability Act (12 U.S.C. 4001 *et seq.*), the Truth in Savings Act (12 U.S.C. 4301 *et seq.*), the Real Estate Settlement Procedures Act (12 U.S.C. 2601 *et seq.*), the Truth in Lending Act (15 U.S.C. 1601 *et seq.*), the Fair Credit Reporting Act (15 U.S.C. 1681 *et seq.*), the Equal Credit Opportunity Act (15 U.S.C. 1691 *et seq.*), the Fair Debt Collection Practices Act (15 U.S.C. 1692 *et seq.*), the Electronic Funds Transfer Act (15 U.S.C. 1693 *et seq.*) and the Fair Housing Act (42 U.S.C. 3601 *et seq.*).

(6) *Civil money penalties assessed pursuant to 12 U.S.C. 1820(e) for refusal to allow examination or to provide required information during an examination*. Pursuant to section 10(e)(4) of the FDIA (12 U.S.C. 1820(e)(4)), civil money penalties may be assessed against any affiliate of an insured depository institution that refuses to permit a duly-appointed examiner to conduct an examination or to provide information during the course of an examination as set forth in section 20(b) of the FDIA (12 U.S.C. 1820(b)), in an amount not to exceed \$8,655 for each day the refusal continues.

(7) *Civil money penalties assessed pursuant to 12 U.S.C. 1820(k) for violation of one-year restriction on Federal examiners of financial institutions*. Pursuant to section 10(k) of the FDIA (12 U.S.C. 1820(k)), the Board of Directors or its designee may assess a civil money penalty of up to \$311,470 against any covered former Federal examiner of a financial institution who, in violation of section 10(k) of the FDIA (12 U.S.C. 1820(k)) and within the one-year period following termination of government service as an employee, serves as an officer, director, or consultant of a financial or depository institution, a holding company, or of any other entity listed in section 10(k) of the FDIA (12 U.S.C. 1820(k)), without the written waiver or permission by the appropriate Federal banking agency or authority under section 10(k)(5) of the FDIA (12 U.S.C. 1820(k)(5)).

(8) *Civil money penalties assessed pursuant to 12 U.S.C. 1828(a) for incorrect display of insurance logo*. Pursuant to section 18(a)(3) of the FDIA (12 U.S.C. 1828(a)(3)), civil money penalties may be assessed against an insured depository institution that fails to correctly display its insurance logo pursuant to that section, in an amount

not to exceed \$118 for each day the violation continues.

(9) *Civil money penalties assessed pursuant to 12 U.S.C. 1828(h) for failure to timely pay assessment.*

(i) *In general.* Subject to paragraph (d)(9)(iii) of this section, any insured depository institution that fails or refuses to pay any assessment shall be subject to a penalty in an amount of not more than 1 percent of the amount of the assessment due for each day that such violation continues.

(ii) *Exception in case of dispute.* Paragraph (d)(9)(i) of this section shall not apply if—

(A) The failure to pay an assessment is due to a dispute between the insured depository institution and the Corporation over the amount of such assessment; and

(B) The insured depository institution deposits security satisfactory to the Corporation for payment upon final determination of the issue.

(iii) *Special rule for small assessment amounts.* If the amount of the assessment that an insured depository institution fails or refuses to pay is less than \$10,000 at the time of such failure or refusal, the amount of any penalty to which such institution is subject under paragraph (d)(9)(i) of this section shall not exceed \$118 for each day that such violation continues.

(iv) *Authority to modify or remit penalty.* The Corporation, in the sole discretion of the Corporation, may compromise, modify, or remit any penalty that the Corporation may assess or has already assessed under paragraph (d)(9)(i) of this section upon a finding that good cause prevented the timely payment of an assessment.

(10) *Civil money penalties assessed pursuant to 12 U.S.C. 1829b(j) for recordkeeping violations.* Pursuant to section 19b(j) of the FDIA (12 U.S.C. 1829b(j)), civil money penalties may be assessed against an insured depository institution and any director, officer or employee thereof who willfully or through gross negligence violates or causes a violation of the recordkeeping requirements of that section or its implementing regulations in an amount not to exceed \$19,787 per violation.

(11) *Civil money penalties pursuant to 12 U.S.C. 1832(c) for violation of provisions regarding interest-bearing demand deposit accounts.* Pursuant to 12 U.S.C. 1832(c), any depository institution that violates the prohibition regarding interest-bearing demand deposit accounts shall be subject to a fine of \$2,750 per violation.

(12) *Civil penalties for violations of security measure requirements under 12 U.S.C. 1884.* Pursuant to 12 U.S.C. 1884,

an institution that violates a rule establishing minimum security requirements as set forth in 12 U.S.C. 1882, shall be subject to a civil penalty not to exceed \$275 for each day of the violation.

(13) *Civil money penalties assessed pursuant to 12 U.S.C. 1972(2)(F) for prohibited tying arrangements.* Pursuant to the Bank Holding Company Act of 1970, Tier One civil money penalties may be assessed pursuant to 12 U.S.C. 1972(2)(F)(i) in an amount not to exceed \$9,468 for each day during which the violation continues. Tier Two civil money penalties may be assessed pursuant to 12 U.S.C. 1972(2)(F)(ii) in an amount not to exceed \$47,340 for each day during which the violation, practice or breach continues. Tier Three civil money penalties may be assessed pursuant to 12 U.S.C. 1972(2)(F)(iii) in an amount not to exceed, in the case of any person other than an insured depository institution \$1,893,610 for each day during which the violation, practice, or breach continues or, in the case of any insured depository institution, an amount not to exceed the lesser of \$1,893,610 or 1 percent of the total assets of such institution for each day during which the violation, practice, or breach continues.

(14) *Civil money penalties assessed pursuant to 12 U.S.C. 3909(d).* Pursuant to the International Lending Supervision Act (ILSA) (12 U.S.C. 3909(d)), civil money penalties may be assessed against any institution or any officer, director, employee, agent or other person participating in the conduct of the affairs of such institution is an amount not to exceed \$2,355 for each day a violation of the ILSA or any rule, regulation or order issued pursuant to ILSA continues.

(15) *Civil money penalties assessed for violations of 15 U.S.C. 78u-2.* Pursuant to section 21B of the Securities Exchange Act of 1934 (Exchange Act) (15 U.S.C. 78u-2), civil money penalties may be assessed for violations of certain provisions of the Exchange Act, where such penalties are in the public interest. Tier One civil money penalties may be assessed pursuant to 15 U.S.C. 78u-2(b)(1) in an amount not to exceed \$8,908 for a natural person or \$89,078 for any other person for violations set forth in 15 U.S.C. 78u-2(a). Tier Two civil money penalties may be assessed pursuant to 15 U.S.C. 78u-2(b)(2) in an amount not to exceed—for each violation set forth in 15 U.S.C. 78u-2(a)—\$89,078 for a natural person or \$445,390 for any other person if the act or omission involved fraud, deceit, manipulation, or deliberate or reckless disregard of a regulatory requirement.

Tier Three civil money penalties may be assessed pursuant to 15 U.S.C. 78u-2(b)(3) for each violation set forth in 15 U.S.C. 78u-2(a), in an amount not to exceed \$178,156 for a natural person or \$890,780 for any other person, if the act or omission involved fraud, deceit, manipulation, or deliberate or reckless disregard of a regulatory requirement; and such act or omission directly or indirectly resulted in substantial losses, or created a significant risk of substantial losses to other persons or resulted in substantial pecuniary gain to the person who committed the act or omission.

(16) *Civil money penalties assessed pursuant to 15 U.S.C. 1639e(k) for appraisal independence violations.* Pursuant to section 1472(a) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Appraisal Independence Rule) (15 U.S.C. 1639e(k)), civil money penalties may be assessed for an initial violation of the Appraisal Independence Rule in an amount not to exceed \$10,875 for each day during which the violation continues and, for subsequent violations, \$21,749 for each day during which the violation continues.

(17) *Civil money penalties assessed for false claims and statements pursuant to 31 U.S.C. 3802.* Pursuant to the Program Fraud Civil Remedies Act (31 U.S.C. 3802), civil money penalties of not more than \$10,781 per claim or statement may be assessed for violations involving false claims and statements.

(18) *Civil money penalties assessed for violations of 42 U.S.C. 4012a(f).* Pursuant to the Flood Disaster Protection Act (FDPA) (42 U.S.C. 4012a(f)), civil money penalties may be assessed against any regulated lending institution that engages in a pattern or practice of violations of the FDPA in an amount not to exceed \$2,056 per violation.

■ 3. Revise 12 CFR 308.502(a)(6), (b)(4), and (d) to read as follows:

§ 308.502 Basis for civil penalties and assessments.

* * * * *

(a) * * *

(6) The amount of any penalty assessed under paragraph (a)(1) of this section will be adjusted for inflation in accordance with § 308.132(d)(17) of this part.

* * * * *

(b) * * *

(4) The amount of any penalty assessed under paragraph (a)(1) of this section will be adjusted for inflation in accordance with § 308.132(d)(17) of this part.

* * * * *

(d) Civil money penalties that are assessed under this subpart are subject to annual adjustments to account for inflation as required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Pub. L. 114–74, sec. 701, 129 Stat. 584) (*see also* 12 CFR 308.132(d)(17)).

* * * * *

PART 327—ASSESSMENTS

■ 4. The authority citation for part 327 continues to read as follows:

Authority: 12 U.S.C. 1441, 1813, 1815, 1817–19, 1821.

■ 5. Revise § 327.3(c) to read as follows:

§ 327.3 Payment of assessments.

* * * * *

(c) *Necessary action, sufficient funding by institution.* Each insured depository institution shall take all actions necessary to allow the Corporation to debit assessments from the insured depository institution's designated deposit account. Each insured depository institution shall, prior to each payment date indicated in paragraph (b)(2) of this section, ensure that funds in an amount at least equal to the amount on the quarterly certified statement invoice are available in the designated account for direct debit by the Corporation. Failure to take any such action or to provide such funding of the account shall be deemed to constitute nonpayment of the assessment. Penalties for failure to timely pay assessments are provided for at 12 CFR 308.132(d)(9).

* * * * *

Dated at Washington, DC, this 21st day of June, 2016.

By order of the Board of Directors,
Federal Deposit Insurance Corporation.

Robert E. Feldman,
Executive Secretary.

[FR Doc. 2016–15027 Filed 6–28–16; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2016–N–1618]

Medical Devices; General and Plastic Surgery Devices; Classification of the Electrosurgical Device for Over-the-Counter Aesthetic Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the electrosurgical device for over-the-counter aesthetic use into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the electrosurgical device for over-the-counter aesthetic use's classification. 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 order is effective June 29, 2016. The classification was applicable on December 18, 2015.

FOR FURTHER INFORMATION CONTACT:

Long Chen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G472, Silver Spring, MD 20993–0002, 301–796–6389, Long.Chen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the 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, 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 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1) of the FD&C Act. Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of

receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On January 13, 2015, EndyMed Medical Ltd., submitted a request for classification of the Newa™ device 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 request 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 request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on December 18, 2015, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 878.4420.