List of Subjects

12 CFR Part 611

Agriculture, Banks, banking, Rural areas.

12 CFR Part 620

Accounting, Agriculture, Banks, banking, Reporting and recordkeeping requirements, Rural areas.

12 CFR Part 630

Accounting, Agriculture, Banks, banking, Organization and functions (Government agencies), Reporting and recordkeeping requirements, Rural areas.

Accordingly, the interim rule amending 12 CFR parts 611, 620, and 630, which was published on March 31, 2014 (79 FR 17854), is adopted as a final rule without changes.

Dated: June 12, 2014.

Dale L. Aultman,

Secretary, Farm Credit Administration Board.

[FR Doc. 2014–14227 Filed 6–17–14; 8:45 am]

BILLING CODE 6705–01–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1081

[Docket No.: CFPB–2013–0030]

RIN 3170–AA29

Rules of Practice for Issuance of Temporary Cease-and-Desist Orders

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule.

SUMMARY: On September 26, 2013, 78 FR 59163, the Consumer Financial Protection Bureau (Bureau) published in the **Federal Register** an interim final rule establishing procedures for the issuance of a temporary cease-and-desist order (TCDO) pursuant to section 1053(c) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), which requires the Bureau to prescribe rules establishing procedures for the conduct of adjudication proceedings. After reviewing and considering the single public comment offered on its interim final rule, the Bureau adopts the interim final rule without change.

DATES: This final rule takes effect on July 18, 2014.

FOR FURTHER INFORMATION CONTACT: John R. Coleman, Senior Counsel, Legal Division, Consumer Financial Protection Bureau, 1700 G Street NW., Washington, DC 20552; at (202) 435–7254.

SUPPLEMENTARY INFORMATION:

I. Background

On June 29, 2012, the Bureau published in the **Federal Register** the final Rules of Practice for Adjudication Proceedings pursuant to sections 1022(b)(1) and 1053(e) of the Dodd-Frank Act, 12 U.S.C. 5512(b)(1) & 5563(e).[1] That final rule, however, does not apply to the issuance of a TCDO pursuant to section 1053(c) of the Dodd-Frank Act.[2] The Bureau previously invited comments as to whether special rules governing such proceedings are necessary and, if so, what the rules should provide.[3] One commenter recommended that the Bureau promulgate rules governing temporary cease-and-desist proceedings initiated pursuant to section 1053(c) of the Dodd-Frank Act and pointed to the Federal Deposit Insurance Corporation's (FDIC) rules governing temporary cease-and-desist proceedings, 12 CFR 308.131, as an example of such rules.[4]

On September 26, 2013, 78 FR 59163, the Bureau published its interim final rule establishing procedures for the issuance of a temporary cease-and-desist order (TCDO) pursuant to section 1053(c) of the Dodd-Frank Act. In developing the interim final rule, the Bureau considered the procedures related to temporary cease-and-desist orders that are followed by other regulatory agencies, including the FDIC, the Securities and Exchange Commission, and the Office of the Comptroller of the Currency. The interim final rule most closely follows the FDIC's approach as codified in 12 CFR 308.131. The Bureau issued the interim final rule to clarify (1) the basis for the issuance of a TCDO; (2) the content, scope, and form of a TCDO; (3) the procedures governing the issuance of a TCDO and the remedies available to the Bureau in issuing a TCDO; and (4) the rights of persons subject to a TCDO.

The interim final rule described each section of the rule and explained the basis of the rule with reference to rules of other agencies as appropriate. After reviewing and considering the single public comment offered, the Bureau adopts the interim final rule without change.

II. Legal Authority

The Bureau promulgates this final rule pursuant to its authority to implement section 1053 of the Dodd-Frank Act, 12 U.S.C. 5563(e), as well as its general rulemaking authority to promulgate rules necessary or appropriate to carry out the Federal consumer financial laws, 12 U.S.C. 5512(b)(1).

III. Public Comment on the Interim Final Rule

In response to the interim final rule, the Bureau received one comment letter that did not contain any specific comments or suggestions pertaining to the interim final rule. Accordingly, the Bureau is adopting the interim final rule without change.

IV. Section 1022(b) Provisions

In developing the interim final and final rules, the Bureau has considered the potential benefits, costs, and impacts and has consulted or offered to consult with the prudential regulators, the Department of Housing and Urban Development, and the Federal Trade Commission, including with regard to consistency with any prudential, market, or systemic objectives administered by such agencies.[5]

The Dodd-Frank Act requires the Bureau to prescribe rules establishing such procedures as may be necessary to carry out section 1053 of the Act, which provides for temporary cease-and-orders in subsection (c). The final rule itself does not impose significant costs upon covered persons, but, consistent with section 1053, provides a straightforward and efficient process for the issuance of a temporary cease-and-desist order, and a direct route to judicial review.

The final rule has no unique impact on insured depository institutions or insured credit unions with $10 billion or less in assets described in section 1026(a) of the Dodd-Frank Act, nor does it have a unique impact on rural consumers.

V. Regulatory Requirements

As the Bureau noted in publishing the interim final rule, this rule relates solely

[1] *See* 77 FR 39058 (June 29, 2012) (codified at 12 CFR Part 1081).

[2] *Id.* at 39058.

[3] *See* 76 FR 45338, 45338 (July 28, 2011).

[4] *See* 77 FR 39058, 39060 (June 29, 2012).

[5] Section 1022(b)(2)(A) of the Dodd-Frank Act calls for the Bureau to consider the potential benefits and costs of a regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services; the impact on depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Dodd-Frank Act; and the impact on consumers in rural areas. Section 1022(b)(2)(B) directs the Bureau to consult with the appropriate prudential regulators or other Federal agencies regarding consistency with objectives those agencies administer. The manner and extent to which these provisions apply to a rulemaking of this kind, which establishes Bureau procedures and imposes no standards of conduct, is unclear. Nevertheless, to inform this rulemaking more fully, the Bureau performed the analyses and consultations described in those provisions of the Dodd-Frank Act.

to agency procedure and practice and, thus, is not subject to the notice and comment requirements of the Administrative Procedure Act, 5 U.S.C. 553(b). Because no notice of proposed rulemaking is required, these regulations are not a ''rule'' as defined by the Regulatory Flexibility Act, 5 U.S.C. 601(2), and no initial or final regulatory flexibility analysis is required.

VI. Paperwork Reduction Act

The Bureau has determined that the regulations in this subpart do not impose any new recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would constitute collections of information requiring approval under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

List of Subjects in 12 CFR Part 1081

Administrative practice and procedure, Banking, Banks, Consumer protection, Credit, Credit unions, Law enforcement, National banks, Savings associations, Trade practices.

Authority and Issuance

For the reasons set forth above, the interim final rule amending 12 CFR part 1081 published at 78 FR 59163, September 26, 2013, is adopted as a final rule without change.

Dated: June_10, 2014.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

[FR Doc. 2014–14228 Filed 6–17–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA–2012–N–0677]

Dental Devices; Reclassification of Blade-Form Endosseous Dental Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify the blade-form endosseous dental implant, a preamendments class III device, into class II (special controls). On its own initiative, based on new information, FDA is revising the classification of blade-form endosseous dental implants.

DATES: This order is effective July 18, 2014.

FOR FURTHER INFORMATION CONTACT: Michael J. Ryan, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993, 301–796–6283, *michael.ryan@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), 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, reflecting 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(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is 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 21 CFR part 807.

A preamendments device that has been classified into class III may be marketed by means of premarket notification procedures (510(k) process) without submission of a premarket approval application (PMA) until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval or until the device is subsequently reclassified into class I or class II.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the mechanism for reclassifying a device from rulemaking to an administrative order.

Section 513(e) of the FD&C Act governs reclassification of classified preamendments devices. This section provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) of the FD&C Act or an interested person may petition FDA to reclassify a preamendments device. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland-Rantos Co.* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see *Bell,* 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 388–391 (D.D.C. 1991)) or in light of changes in ''medical science'' (*Upjohn,* 422 F.2d at 951). Whether data before the Agency are old or new data, the ''new information'' to support reclassification under section 513(e) of the FD&C Act must be ''valid scientific evidence,'' as defined in section 513(a)(3) and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Manufacturers Association* v. *FDA,* 766