by adding the entry for § 665.20 in numerical order to read as follows:

§ 902.1 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

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(b) * * *

CFR part or section where the information collection requirement is located	Current OMB control No. (all numbers begin with 0648–)
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50 CFR	
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665.20	–0612
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[FR Doc. 2010–28075 Filed 11–4–10; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. FDA–2008–N–0273]

Medical Devices; Radiology Devices; Reclassification of Full-Field Digital Mammography System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the reclassification of the full-field digital mammography (FFDM) system from class III (premarket approval) to class II (special controls). The device type is intended to produce planar digital x-ray images of the entire breast; this generic type of device may include digital mammography acquisition software, full-field digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories. The special control that will apply to the device is the guidance document entitled "Class II Special Controls Guidance Document: Full-Field Digital Mammography System." FDA is reclassifying the device into class II (special controls) because general controls along with special controls will provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

DATES: This rule is effective December 6, 2010.

FOR FURTHER INFORMATION CONTACT:

Mary Pastel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G304, Silver Spring, MD 20993–0002, 301–796–6887; or

Kyle J. Myers, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, rm. 3118, Silver Spring, MD 20993–0002, 301–796–2533.

SUPPLEMENTARY INFORMATION:

I. Statutory Framework for Device Classification

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (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), and the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), 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 1976 amendments), as "preamendments devices." FDA classifies these devices after the Agency has taken the following steps:

1. Receives a recommendation from a device classification panel (an FDA advisory committee);

2. Publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and

3. Publishes a final regulation classifying the device type.

FDA has classified most preamendments devices under these procedures.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as "postamendments devices." These devices are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These device types remain in class III and require premarket approval, unless and until:

1. FDA reclassifies the device type into class I or II;

2. FDA issues an order classifying the device type into class I or II in accordance with section 513(f)(2) of the FD&C Act, as amended by FDAMA; or

3. FDA issues an order finding the device to be substantially equivalent, under 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 of the regulations.

Reclassification of classified postamendments devices is governed by section 513(f)(3) of the FD&C Act. This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the FD&C Act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device into class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of these class III devices. To change the classification of the device, the proposed new class must

have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Under section 513(f)(3)(B)(i) of the FD&C Act, the Secretary may ask for a recommendation from a device classification panel on a proposed reclassification, whether initiated by FDA or a petitioner. The panel will make a recommendation to FDA concerning the proposed reclassification. The recommendation must contain the following information: (1) A summary of the reasons for the recommendation, (2) a summary of the data upon which the recommendation is based, and (3) an identification of the risks to health (if any) presented by the device that is the subject of the proposed reclassification.

Following the effective date of this final rule, any firm submitting a 510(k) for an FFDM system will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

II. Regulatory History of the Device

An FFDM system is a postamendments device classified into class III under section 513(f)(1) of the FD&C Act. This generic type of device cannot be placed in commercial distribution unless it is reclassified under section 513(f)(3) of the FD&C Act or subject to an approval of a premarket approval (PMA) application under section 515 of the FD&C Act (21 U.S.C. 360e). In accordance with section 513(f)(3) of the FD&C Act and based on information regarding the device, FDA, on its own initiative, is reclassifying this device type from class III to class II when intended to produce planar digital x-ray images of the entire breast. This generic type of device may include digital mammography acquisition software, full-field digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories. Consistent with the FD&C Act and the regulation, FDA referred the proposed reclassification to the Radiological Devices Panel (the Panel) for its recommendation on the requested change in classification.

At a public meeting on May 23, 2006, the Panel unanimously recommended that the FFDM system be reclassified from class III to class II (special controls). The Panel believed that class II with a special controls guidance document, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device (Ref. 1).

Accordingly, in the **Federal Register** of May 30, 2008 (73 FR 31040), FDA issued a proposed rule to reclassify the device, full-field digital mammography system, from class III (premarket approval) into class II (special controls). FDA invited interested persons to comment on the proposed rule by August 28, 2008.

A second meeting of the Panel was held on November 17, 2009. This meeting was called because the comments received on the proposed rule raised the following new questions: Are separate data needed to demonstrate the equivalence of FFDM for screening and diagnosis indications? Are statistically significant clinical studies needed to demonstrate equivalence or can equivalence be demonstrated with laboratory and phantom studies along with limited clinical demonstrations? Are clinical data on various subgroups necessary to demonstrate equivalence?

The Panel unanimously recommended that the FFDM system be reclassified from class III to class II (special controls). The Panel also indicated that separate data are necessary for screening and diagnostic claims; that laboratory and phantom studies with limited clinical demonstration are adequate to establish equivalence; and that subcategory analysis is unnecessary.

III. Summary of Final Rule

The final rule contains revisions to the identification of the device type, FFDM system in the draft classification regulation, 21 CFR 892.1715. The final rule uses the term "planar" instead of "full-field" to describe digital x-ray images of the entire breast. The sentence stating what the generic type of device may include was revised by adding automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories, and by eliminating signal analysis programs. This change was made to clarify the description by explicitly listing aspects of the device and excluding signal analysis programs that are contained within the display devices, which are regulated separately. Display devices are not part of the FFDM system but rather are separate class II devices. The identification now reads: Intended to produce planar digital x-ray images of the entire breast. This generic type of device may include digital mammography acquisition software, full-field digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories.

IV. Comments and FDA's Response

During the public comment period, 23 respondents submitted comments. The comments included manufacturers, professional organizations, trade associations, and individual medical professionals. All comments supported the reclassification of the FFDM system from class III (premarket approval) to class II (special controls).

(Comment 1) One comment suggested that the identification's use of the term "signal analysis" can be confusing in the context of FFDM systems and suggested that some items were not completely incorporated into the FFDM identification from the film/screen identification that should have been incorporated for clarity. The comment suggested that the regulation use the following identification to address those concerns: A full-field digital mammography system is a device intended to produce full-field digital x-ray images of the breast. This generic type of device may include one or more of the following: Digital mammography acquisition software, full-field digital image receptor, acquisition workstation, automatic exposure control, and image processing and reconstruction programs, patient and equipment supports, component parts, and accessories.

(Response) FDA agrees with the comment and has revised the identification to be similar to the language suggested by the comment.

V. FDA's Conclusions

Based on the information discussed in the preamble to the proposed rule (73 FR 31040) and comments on the proposed rule and draft special controls guidance, FDA concludes that special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the full-field digital mammography system. The Agency is reclassifying the full-field digital mammography system from class III (premarket approval) to class II (special controls) when intended to produce planar digital x-ray images of the entire breast. This generic type of device may include digital mammography acquisition software, full-field digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Full-Field Digital Mammography System" that the Agency intends to use as the special control for this device. The guidance addresses the information FDA believes should be included in a premarket notification submission (510(k)) for the FFDM system. FDA has identified the risks to health associated with the use of the device in the first column of table 1 of the special controls guidance document. The recommended mitigation measures are identified in the second column of table 1 of the special controls guidance document.

VI. 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.

VII. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action under the Executive order.

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

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

FFDM devices are intended to produce planar digital x-ray images of the entire breast. This generic type of device may include digital mammography acquisition software, full-field digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories. Based on the history of use of this type of device since the first PMA was approved in 2000, FDA concludes that reclassification from class III into class II (special controls) would ensure safety and effectiveness of these devices without undue regulatory burden. Manufacturers must address the issues identified by the special controls guidance document. Manufacturers of new or modified FFDM devices would be subject to premarket notification requirements, but the burden of submitting a 510(k) would be substantially less than that of preparing a PMA.

VIII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to "construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." Federal law includes an express preemption provision that preempts certain State requirements "different from or in addition to" certain Federal requirements applicable to devices. 21 U.S.C. 360k; *See Medtronic* v. *Lohr* 518 U.S. 470 (1996); *Riegel* v. *Medtronic,* 552 U.S. 312 (2008). The special controls established by this final rule create "requirements" to address each identified risk to health presented by these specific medical devices under 21 U.S.C. 360k, even though product sponsors may have flexibility in how they meet those requirements. Cf. *Papike* v. *Tambrands, Inc.,* 107 F.3d 737, 740–42 (9th Cir. 1997).

IX. Paperwork Reduction Act of 1995

This final rule establishes as special controls a guidance document that refers to previously approved collections of information found in 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). Elsewhere in this issue of the **Federal Register**, FDA is issuing a document announcing the availability of the guidance document that will serve as the special control for this device. That document contains an analysis of the paperwork burden for the guidance document.

X. References

The following references have been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Radiological Devices Panel, Transcript, pp. 142–156, available at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/details.cfm?mtg=659,* May 23, 2006.

2. Pisano, E., C. Gatsonis, E. Hendrick, *et al.,* "Digital Mammographic Imaging Screening Trial (DMIST) Investigators Group," "Diagnostic Performance of Digital Versus Film Mammography for Breast-Cancer Screening," *New England Journal of Medicine,* 353: 1773–1783, 2005.

3. Yaffe, M., A. Bloomquist, G. Mawdsley, *et al.,* "Quality Control for Digital Mammography: Part II Recommendations From the ACRIN DMIST Trial," *Medical Physics,* 33(3): 737–752, 2006.

4. Thomas, J., K. Chakrabarti, R. Kaczmarek, *et al.,* "Contrast Detail Phantom Scoring Methodology," *Medical Physics,* 32(3), 807, 2005.

5. Device Recalls Are Described in FDA's Briefing Information, Slide Number 12, available at *http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4219b1_04_draft%20FDA%20presentation.pdf,* May 23, 2006.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

PART 892—RADIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 892 continues to read as follows:

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

■ 2. Section 892.1715 is added to subpart B to read as follows:

§ 892.1715 Full-field digital mammography system.

(a) *Identification.* A full-field digital mammography system is a device intended to produce planar digital x-ray images of the entire breast. This generic type of device may include digital mammography acquisition software, full-field digital image receptor, acquisition workstation, automatic exposure control, image processing and reconstruction programs, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II (special controls). The special control for the device is FDA's guidance document entitled "Class II Special Controls Guidance Document: Full-Field Digital Mammography System." *See* § 892.1(e) for the availability of this guidance document.

Dated: November 2, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–28007 Filed 11–4–10; 8:45 am]

BILLING CODE 4160–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4003 and 4903

Debt Collection

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's (PBGC) regulation on debt collection to conform to the Debt Collection Improvement Act of 1996, the Federal Claims Collection Standards and other legal requirements applicable to the collection of non-tax debts owed to PBGC. PBGC is adding salary offset and administrative wage garnishment to the collection methods allowed under the current regulation and making other changes to strengthen PBGC's debt collection program.

DATES: Effective December 6, 2010 (*See* Applicability in **SUPPLEMENTARY INFORMATION**.)

FOR FURTHER INFORMATION CONTACT: Margaret E. Drake, Attorney, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026; 202–326–4400 (extension 3228). (For TTY/TDD users, call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4400 (extension 3228)).

SUPPLEMENTARY INFORMATION: This final rule revises and replaces BGC's debt collection regulations found at 29 CFR Part 4903 to conform to the Debt Collection Improvement Act of 1996 (DCIA), Public Law 104–134, 110 Stat. 1321, 1358 (April 26, 1996), the revised Federal Claims Collection Standards, 31 CFR Chapter IX (Parts 900 through 904), and other laws applicable to the collection of non-tax debt owed to the Government.

Background

In 1994, PBGC adopted a regulation on debt collection to provide procedures to implement administrative offset, as authorized by the Federal Claims Collection Act of 1966, as amended by the Debt Collection Act of 1982 (31 U.S.C. 3701, *et seq.*), and in accordance with regulations issued by the Department of Justice and the General Accountability Office. In 1995, PBGC adopted a regulation on debt collection to provide procedures to implement tax refund offset, as required for participation in the Federal tax refund offset program authorized by 31 U.S.C. 3720A and in accordance with regulations issued by the Treasury Department. Together, these regulations comprise PBGC's current debt collection regulation (29 CFR part 4903) providing procedures for debt collection through administrative offset and tax refund offset. Administrative offset allows PBGC to request that debts owed to PBGC by a debtor (*e.g.,* in connection with government contractual obligations) be offset by amounts another Federal agency may owe to the debtor. Likewise, other Federal agencies may request the collection of debts owed to them be offset by amounts PBGC may owe the debtor. Tax refund offset allows PBGC to request that debts owed to PBGC by a debtor be offset by amounts the Government may owe to the debtor. The Debt Collection Improvement Act of 1996 (DCIA) fundamentally changed the manner in which the Federal government is required to manage the collection of its delinquent debts. Under DCIA, Congress directed that the management of delinquent obligations is to be centralized at the Treasury Department in order to increase the efficiency of the Government's collection efforts.

Pursuant to 31 U.S.C. 3716, to utilize the administrative offset tools under DCIA, Federal agencies had to "adopt, without change, regulations on collecting by administrative offset promulgated by the Department of Justice, the Government Accountability Office, or the Department of the Treasury," or promulgate their own regulations consistent with the regulations issued by the Department of Justice, the General Accountability Office, or the Department of the Treasury. On November 20, 2000, the Department of Justice and the Department of the Treasury revised the FCCS. 65 FR 70390 (Nov. 20, 2000).

On July 22, 2010 (at 75 FR 42662), PBGC published a proposed rule to revise its regulation on debt collection to conform the Debt Collection Improvement Act of 1996, the Federal Claims Collections Standards, other legal requirements applicable to non-tax debts owed to PBGC, and to add salary offset and administrative wage garnishment to the collection methods allowed under the current regulation and make other changes to strengthen PBGC's debt collection program. PBGC received no public comments on the proposed rule and the final regulation is unchanged from the proposed regulation.

Overview of Final Rule

This final regulation revises the procedures for the collection of non-tax debts owed to PBGC through administrative offset and tax refund offset. It adopts the FCCS and supplements it by prescribing procedures consistent with the FCCS, as necessary and appropriate for PBGC operations. The final regulation also provides for the collection of debts via salary offset and the use of administrative wage garnishment. Salary offset is the collection of debt owed by a Federal employee by withholding up to 15 percent of the employee's disposable pay. The procedures for salary offset are governed by 5 U.S.C. 5514, and Office of Personnel Management (OPM) regulations (5 CFR part 550, subpart k). OPM regulations provide for salary offset through the Treasury Offset Program.[1] Administrative wage

[1] PBGC has an internal directive which provides procedures to recover debts owed to PBGC from the current pay account of an employee, and to process

Continued