interim measures with respect to this court order. See *https://www.bis.doc.gov/index.php/component/docman/?task=doc_download&gid=2535.* For additional information about the court ordered injunction pertaining to revisions to the U.S. *https://www.pmddtc.state.gov/ddtc_public?id=ddtc_public_portal_news_and_events&timeframe=week.*

Dated: March 16, 2020.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2020–05934 Filed 4–1–20; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 801, 803, 807, 814, 820, 821, 822, 830, 860, 884, 900, and 1002

[Docket No. FDA–2020–N–0011]

Medical Devices; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending its medical device regulations. These revisions are necessary to reflect changes to the Agency's Center for Devices and Radiological Health's organizational structure, including the reorganization of its offices. The revisions replace references to the obsolete offices and positions with the current information, update the physical addresses for such offices, and correct inaccurate citations. In addition, as part of this effort we made other editorial non-substantive changes to correct other addresses, references, and citations, as appropriate. The rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective April 1, 2020.

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Office of Policy, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993–0002, 301–796–5837.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Center for Devices and Radiological Health (CDRH) has reorganized (84 FR 22854, May 20, 2019) to create an agile infrastructure that can adapt to future organizational, regulatory, and scientific needs. The goal of this change is to implement more efficient, consistent work processes across CDRH that better support and advance CDRH's public health mission and vision. The reorganization will integrate CDRH's premarket and postmarket program functions along product lines, allowing experts to leverage their knowledge to optimize decision making across the product life cycle. Implementation took a phased approach starting on March 18, 2019, and was completed on September 30, 2019.

Historically, CDRH has been organized according to the stage of the product's life cycle, *e.g.,* premarket review, postmarket surveillance, and compliance, rather than by the type of product regulated. The reorganization integrates these functions by product type within the Office of Product Evaluation and Quality (OPEQ). OPEQ was formed by combining the Office of Compliance, the Office of Device Evaluation, the Office of Surveillance and Biometrics, and the Office of In Vitro Diagnostics and Radiological Health into one super office focused on a Total Product Lifecycle approach to medical device oversight. Within OPEQ, there are offices divided by product type, referred to as Offices of Health Technology (OHT), as well as cross-cutting offices focusing on specific policy and programmatic needs including the Office of Regulatory Programs and the Office of Clinical Evidence and Analysis. In addition, the reorganization established the Office of Policy, which includes two teams, the Guidance, Legislation and Special Projects Team and the Regulatory Documents and Special Projects Team, with no changes in the functions for CDRH Policy. The reorganization also established the Office of Strategic Partnerships and Technology Innovation (OST), which combined the Science and Strategic Partnerships, Digital Health, Health Informatics and Innovation teams. There are no changes in functions within the different OST teams. CDRH reorganization also realigned Management Services within the Center to ensure administrative functions in CDRH are optimally aligned, structured, and deliver excellent service. The reorganization streamlined the Center's communication functions, by combining the internal and external communication functions, including CDRH Executive Secretary and Speaker Liaison, into the renamed Division of Communication in the Office of Communication and Education, and created an Internal Communication Branch. The structure of the Office of Science and Engineering Laboratories remains unchanged.

As part of this effort, we are also making other editorial non-substantive changes to correct other addresses, references, and citations, as appropriate.

II. Description of the Technical Amendments

The regulations specified in this rule have been revised to replace all references to ''Office of Device Evaluation'', ''Office of Compliance'', ''Office of Surveillance and Biometrics'' with ''Office of Product Evaluation and Quality,'' and where, appropriate, we have used the term ''Office,'' ''Division,'' ''Team'' or ''Office of Health Technology'' to reflect the responsible unit within CDRH. We have also made conforming edits, as appropriate. In addition, because of the reorganization, the physical location for many of the offices changed, and thus, we have made non-substantive amendments to ensure that the room numbers and addresses reflect the current information, and other changes as necessary to update outdated addresses, references, and citations in the regulations pertaining to medical devices. The rule does not impose any new regulatory requirements on affected parties. The amendments are editorial in nature and should not be construed as modifying any substantive standards or requirements.

III. Notice and Public Comment

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). Section 553 of the Administrative Procedure Act (APA) exempts ''rules of agency organization, procedure, or practice'' from proposed rulemaking (*i.e.,* notice and comment rulemaking). 5 U.S.C. 553(b)(3)(A). Rules are also exempt when an agency finds ''good cause'' that notice and comment rulemaking procedures would be ''impracticable, unnecessary, or contrary to the public interest.'' 5 U.S.C. 553(b)(3)(B).

FDA has determined that this rulemaking meets the notice and comment exemption requirements in 5 U.S.C. 553(b)(3)(A) and (B). FDA's revisions make technical or non-substantive changes that pertain solely to the CDRH reorganization and office move and do not alter any substantive

standard. FDA does not believe public comment is necessary for these minor revisions.

The APA allows an effective date less than 30 days after publication as ''provided by the agency for good cause found and published with the rule'' (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Parts 803 and 821

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Parts 820 and 822

Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 830

Administrative practice and procedure, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 860

Administrative practice and procedure, Medical devices.

21 CFR Part 884

Medical Devices.

21 CFR Part 900

Electronic products, Health facilities, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

21 CFR Part 1002

Electronic products, Radiation protection, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 5, 801, 803, 807, 814, 820, 821, 822, 830, 860, 884, 900, and 1002 are amended as follows:

PART 5—ORGANIZATION

■ 1. The authority citation for part 5 continues to read as follows:

Authority: 5 U.S.C. 552; 21 U.S.C. 301–397.

■ 2. In § 5.1100, revise the entries for ''*Center for Devices and Radiological Health*'' through ''*Office of In Vitro Diagnostics and Radiological Health*'' to read as follows:

§ 5.1100 Headquarters.

* * * * *

Center for Devices and Radiological Health.[12]
Office of the Center Director.
Quality Management Staff.
Office of Communication and Education.
Digital Communication Media Staff.
Program Management Operations Staff.
Division of Communication.
External Communications Branch.
Web and Graphics Branch.
Internal Communication Branch.
Division of Employee Training and Development.
Employee Development Branch.
Technology and Learning Management Branch.
Division of Industry and Consumer Education.
Premarket Programs Branch.
Postmarket and Consumer Branch.
Division of Information Disclosure.
Freedom of Information Branch A.
Freedom of Information Branch B.
Office of Management.
Planning and Program Analysis Staff.
Division of Acquisition Services.
Advanced Acquisitions.
Simplified Acquisitions.
Acquisition Planning Assistance.
Division of Workforce Management.
Recruitment.
Human Capital Management.
Special Programs.
Division of Management Services.
Travel and Conference Management.
Committee Management and Planning.
Space and Facilities Management.
Division of Financial Management.
Budget Formulation.
Budget Execution.
Financial Accountability.
Office of Policy.
Guidance, Legislation and Special Projects.
Regulatory Documents and Special Projects.
Office of Product Evaluation and Quality.
Quality and Analytics Staff.
Clinical and Scientific Policy Staff.
Strategic Initiatives Staff.
Regulation, Policy and Guidance Staff.
Compliance and Quality Staff.
Operations Staff.
Office of Regulatory Programs.
Division of Regulatory Programs 1 (Division of Submission Support).
Division of Regulatory Programs 2 (Division of Establishment Support).
Division of Regulatory Programs 3 (Division of Market Intelligence).
Office of Clinical Evidence and Analysis.
Division of Clinical Evidence and Analysis 1 (Division of Clinical Science and Quality).
Division of Clinical Evidence and Analysis 2 (Division of Biostatistics).
Office of Health Technology 1 (OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices).
Division of Health Technology 1A (Division of Ophthalmic Devices).
Division of Health Technology 1B (Division of Dental Devices).
Division of Health Technology 1C (Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices).
Office of Health Technology 2 (OHT2: Office of Cardiovascular Devices).
Division of Health Technology 2A (Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices).
Division of Health Technology 2B (Division of Circulatory Support, Structural and Vascular Devices).
Division of Health Technology 2C (Division of Coronary and Peripheral Interventional Devices).
Office of Health Technology 3 (OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices).
Division of Health Technology 3A (Division of Renal, Gastrointestinal, Obesity, and Transplant Devices).
Division of Health Technology 3B (Division of Reproductive, Gynecology and Urology Devices).
Division of Health Technology 3C

[12] Mailing address: 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993.

(Division of Drug Delivery and General Hospital Devices, and Human Factors).
Office of Health Technology 4 (OHT4: Office of Surgical and Infection Control Devices).
Division of Health Technology 4A (Division of General Surgery Devices).
Division of Health Technology 4B (Division of Infection Control and Plastic Surgery Devices).
Office of Health Technology 5 (OHT5: Office of Neurological and Physical Medicine Devices).
Division of Health Technology 5A (Division of Neurological, Neurointerventional and Neurodiagnostic Devices).
Division of Health Technology 5B (Division of Neuromodulation and Physical Medicine Devices).
Office of Health Technology 6 (OHT6: Office of Orthopedic Devices).
Division of Health Technology 6A (Division of Joint Arthroplasty Devices).
Division of Health Technology 6B (Division of Spinal Devices).
Division of Health Technology 6C (Division of Stereotaxic, Trauma and Restorative, Devices).
Office of Health Technology 7 (OHT7: Office of In Vitro Diagnostics and Radiological Health).
Division of Program Operations and Management.
Division of Chemistry and Toxicology Devices.
Chemistry Branch.
Diabetes Branch.
Toxicology Branch.
Cardio-Renal Diagnostics Branch.
Division of Molecular Genetics and Pathology.
Molecular Pathology and Cytology Branch.
Molecular Genetics Branch.
Division of Immunology and Hematology Devices.
Hematology Branch.
Immunology and Flow-Cytometry Branch.
Division of Microbiology Devices.
Viral Respiratory and HPV Branch.
General Viral and Hepatitis Branch.
General Bacterial and Antimicrobial Susceptibility Branch.
Bacterial Respiratory and Medical Countermeasures Branch.
Division of Radiological Health.
Magnetic Resonance and Electronic Products Branch.
Diagnostic X-Ray Systems Branch.
Nuclear Medicine and Radiation Therapy Branch.
Mammography, Ultrasound and Imaging Software Branch.
Division of Mammography Quality Standards.
Office of Science and Engineering Laboratories.
Immediate Office of the Director
Division of Applied Mechanics.
Division of Biomedical Physics.
Division of Biology, Chemistry and Materials Science.
Division of Imaging, Diagnostics, and Software Reliability.
Division of Administrative and Laboratory Support.
Office of Strategic Partnerships and Technology Innovation.
Innovation.
Division of All Hazards Response Science and Strategic Partnerships.
Medical Device Development Tools.
Health of Women.
Pediatrics and Special Populations.
All Hazards Readiness Response and Cybersecurity.
Patient Science and Engagement.
Partnerships to Advance Innovation and Regulatory Science.
Science and Special Projects Incubator.
Standards and Conformity Assessment Program.
Division of Digital Health.
Operational Excellence.
Technical and Policy Leadership Strategic Partnerships and Initiatives 1.
Technical and Policy Leadership Strategic Partnerships and Initiatives 2.
Strategic Initiatives and Special Projects.
Division of Technology and Data Services.
Business and Transformation Services.
Data Services.
Technology Services.

* * * * *

PART 801—LABELING

■ 5. The authority citation for part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360d, 360i, 360j, 371, 374.

■ 6. In § 801.55, revise paragraph (b)(2) to read as follows:

§ 801.55 Request for an exception from or alternative to a unique device identifier requirement.

* * * * *

(b) * * *

(2) In all other cases, by email to: *GUDIDSupport@fda.hhs.gov,* or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3293, Silver Spring, MD 20993–0002.

* * * * *

■ 7. In § 801.57, revise paragraph (c)(2) to read as follows:

§ 801.57 Discontinuation of legacy FDA identification numbers assigned to devices.

* * * * *

(c) * * *

(2) No later than September 24, 2014, the labeler submits, and obtains FDA approval of, a request for continued use of the assigned labeler code. A request for continued use of an assigned labeler code must be submitted by email to: *GUDIDSupport@fda.hhs.gov,* or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3293, Silver Spring, MD 20993–0002.

* * * * *

PART 803—MEDICAL DEVICE REPORTING

■ 8. The authority citation for part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

■ 9. In § 803.11, revise paragraph (d) to read as follows:

§ 803.11 What form should I use to submit reports of individual adverse events and where do I obtain these forms?

* * * * *

(d) Form FDA 3500A is available on the internet at *https://www.accessdata.fda.gov/scripts/medwatch/index.cfm.*

■ 10. In § 803.19(b), revise the second sentence to read as follows:

§ 803.19 Are there exemptions, variances, or alternative forms of adverse event reporting requirements?

* * * * *

(b) * * * You must submit the request to us in writing at the following address: MDR Exemption Requests, Medical Device Report (MDR) Team, Division of Regulatory Programs 3, Office of Regulatory Programs, Office of Product Evaluation and Quality, 10903 New Hampshire Ave., Bldg. 66, Rm.1523, Silver Spring, MD 20993–0002. * * *

* * * * *

■ 11. In § 803.21, revise paragraph (a) to read as follows:

§ 803.21 Where can I find the reporting codes for adverse events that I use with medical device reports?

(a) The MedWatch Medical Device Reporting Code Instruction Manual contains adverse event codes for use with Form FDA 3500A. You may obtain the coding manual from FDA's website

at: *https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/mdr-adverse-event-codes.*

* * * * *

■ 12. In § 803.33, revise paragraph (a) to read as follows:

§ 803.33 If I am a user facility, what must I include when I submit an annual report?

(a) You must submit to us an annual report on Form FDA 3419. You must submit an annual report by January 1, of each year. You may obtain this form on the internet at: *https://www.fda.gov/media/72292/download.*

* * * * *

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

■ 13. The authority citation for part 807 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 360bbb-8b, 371, 374, 379k–1, 381, 393; 42 U.S.C. 264, 271.

■ 14. In § 807.21, revise paragraph (b) introductory text to read as follows:

§ 807.21 How to register establishments and list devices.

* * * * *

(b) If the information under § 807.21(a) cannot be submitted electronically, a waiver may be requested. Waivers will be granted only if use of electronic means is not reasonable for the person requesting the waiver. To request a waiver, applicants must send a letter to the Imports and Registration and Listing Team, Division of Regulatory Programs 2, Office of Regulatory Programs, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.1432, Silver Spring, MD 20993–0002, that includes the following information:

* * * * *

■ 15. In § 807.34, revise paragraph (a) to read as follows:

§ 807.34 Summary of requirements for owners or operators granted a waiver from submitting required information electronically.

(a) For initial registration and listing, owners or operators who have been granted a waiver from electronic filing using the procedures set forth in § 807.21(b) must send a letter containing all of the registration and listing information described in §§ 807.22, 807.25 (and § 807.26 when such information is requested by FDA), at the times described in § 807.22, to: The Imports and Registration and Listing Team, Division of Regulatory Programs 2, Office of Regulatory Programs, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1432, Silver Spring, MD 20993–0002.

* * * * *

■ 16. In § 807.37, revise paragraph (a) to read as follows:

§ 807.37 Public availability of establishment registration and device listing information.

(a) Establishment registration and device listing information is available for public inspection in accordance with section 510(f) of the Federal Food, Drug, and Cosmetic Act and will be posted on the FDA website, with the exception of the information identified in paragraph (b) of this section. Requests for information by persons who do not have access to the internet should be directed to the Imports and Registration and Listing Team, Division of Regulatory Programs 2, Office of Regulatory Programs, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm.1432, Silver Spring, MD 20993–0002. In addition, there will be available for inspection at each of the Food and Drug Administration district offices the same information for firms within the geographical area of such district offices. Upon request, verification of a registration number or location of a registered establishment will be provided.

* * * * *

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

■ 17. The authority citation for part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 360bbb–8b, 371, 372, 373, 374, 375, 379, 379e, 379k–1, 381.

■ 18. In § 814.42, revise paragraph (d)(2) to read as follows:

§ 814.42 Filing a PMA.

* * * * *

(d) * * *

(2) Request in writing within 10 working days of the date of receipt of the notice refusing to file the PMA, an informal conference with the Director of the associated Office of Health Technology to review FDA's decision not to file the PMA. FDA will hold the informal conference within 10 working days of its receipt of the request and will render its decision on filing within 5 working days after the informal conference. If, after the informal conference, FDA accepts the PMA for filing, the date of filing will be the date of the decision to accept the PMA for filing. If FDA does not reverse its decision not to file the PMA, the applicant may request reconsideration of the decision from the Director of the Office of Product Evaluation and Quality, the Director of the Center for Biologics Evaluation and Research, or the Director of the Center for Drug Evaluation and Research, as applicable. The Director's decision will constitute final administrative action for the purpose of judicial review.

* * * * *

■ 19. In § 814.100, revise paragraph (e)(2) to read as follows:

§ 814.100 Purpose and scope.

* * * * *

(e) * * *

(2) Submitting an HDE to the Office of Product Evaluation and Quality (OPEQ), Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), or the Center for Drug Evaluation and Research (CDER), as applicable.

* * * * *

PART 820—QUALITY SYSTEM REGULATION

■ 20. The authority citation for part 820 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

■ 21. In § 820.1, revise paragraph (e)(1) to read as follows:

§ 820.1 Scope.

* * * * *

(e) * * * (1) Any person who wishes to petition for an exemption or variance from any device quality system requirement is subject to the requirements of section 520(f)(2) of the Federal Food, Drug, and Cosmetic Act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the FDA's administrative procedures. For guidance on how to proceed for a request for a variance, contact Division of Regulatory Programs 2, Office of Regulatory Programs, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1438, Silver Spring, MD 20993–0002.

* * * * *

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

■ 22. The authority citation for part 821 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, 374.

■ 23. In § 821.2, revise paragraph (b) introductory text to read as follows:

§ 821.2 Exemptions and variances.

* * * * *

(b) A request for an exemption or variance shall be submitted in the form of a petition under § 10.30 of this chapter and shall comply with the requirements set out therein, except that a response shall be issued in 90 days. The Director or Deputy Directors, CDRH, or the Director of the Office of Regulatory Program, CDRH, shall issue responses to requests under this section. The petition shall also contain the following:

* * * * *

PART 822—POSTMARKET SURVEILLANCE

■ 24. The authority citation for part 822 continues to read as follows:

Authority: 21 U.S.C. 331, 352, 360i, 360l, 371, 374.

■ 25. In § 822.7, revise paragraph (a)(1) to read as follows:

§ 822.7 What should I do if I do not agree that postmarket surveillance is appropriate?

(a) * * *

(1) Requesting a meeting with the individual who issued the order for postmarket surveillance;

* * * * *

■ 26. In § 822.22, revise paragraph (a)(1) to read as follows:

§ 822.22 What recourse do I have if I do not agree with your decision?

(a) * * *

(1) Requesting a meeting with the individual who issued the order for postmarket surveillance;

* * * * *

PART 830—UNIQUE DEVICE IDENTIFICATION

■ 27. The authority citation for part 830 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 352, 353, 360, 360d, 360i, 360j, 371.

* * * * *

■ 28. In § 830.110, revise paragraph (a)(1) to read as follows:

§ 830.110 Application for accreditation as an issuing agency.

(a) * * *(1) An applicant seeking initial FDA accreditation as an issuing agency shall notify FDA of its desire to be accredited by sending a notification by email to: *GUDIDSupport@fda.hhs.gov,* or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3293, Silver Spring, MD 20993–0002.

* * * * *

■ 29. In § 830.320, revise paragraphs (c)(1) and (3) to read as follows:

§ 830.320 Submission of unique device identification information.

* * * * *

(c) * * * (1) A labeler may request a waiver from electronic submission of UDI data by submitting a letter addressed to the appropriate Center Director explaining why electronic submission is not technologically feasible; send the request by email to: *udi@fda.hhs.gov,* or by correspondence to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3293, Silver Spring, MD 20993–0002.

* * * * *

(3) A labeler that has a waiver from electronic submission of UDI data must send a letter containing all of the information required by § 830.310, as well as any ancillary information permitted to be submitted under § 830.340 that the labeler wishes to submit, within the time permitted by § 830.330, addressed to: UDI Regulatory Policy Support, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3293, Silver Spring, MD 20993–0002.

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

■ 30. The authority citation for part 860 continues to read as follows:

Authority: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

■ 31. In § 860.123, revise paragraph (b)(1) to read as follows:

§ 860.123 Reclassification petition: Content and form.

* * * * *

(b) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Policy Staff, 10903 New Hampshire Ave., Bldg. 66, Rm. 5445, Silver Spring, MD 20993–0002; for devices regulated by the Center for Biologics Evaluation and Research, addressed to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002; for devices regulated by the Center for Drug Evaluation and Research, addressed to the Food and Drug Administration, Center for Drug Evaluation and Research, Central Document Control Room, 5901–B Ammendale Rd., Beltsville, MD 20705–1266, as applicable.

* * * * *

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 32. The authority citation for part 884 continues to read as follows:

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

■ 33. In § 884.5360, remove and reserve paragraph (c).

PART 900—MAMMOGRAPHY

■ 34. The authority citation for part 900 continues to read as follows:

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

■ 35. In § 900.3, revise paragraph (b)(1) to read as follows:

§ 900.3 Application for approval as an accreditation body.

* * * * *

(b) * * *(1) An applicant seeking initial FDA approval as an accreditation body shall inform the Division of Mammography Quality Standards, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3621, Silver Spring, MD 20993, Attn: Program Management Branch, of its desire to be approved as an accreditation body and of its requested scope of authority.

* * * * *

■ 36. In § 900.15, revise paragraph (d)(3)(i) to read as follows:

§ 900.15 Appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification.

* * * * *

(d) * * *

(3) * * *

(i) A facility must request reconsideration by DMQS within 60 days of the accreditation body's adverse

appeals decision, at the following address: Food and Drug Administration, Center for Devices and Radiological Health, Division of Mammography Quality Standards, Attn: Facility Accreditation Review Committee, 10903 New Hampshire Ave., Bldg. 66, Rm. 3621, Silver Spring, MD 20993–0002.

* * * * *

■ 37. In § 900.18, revise paragraph (c) introductory text to read as follows:

§ 900.18 Alternative requirements for § 900.12 quality standards.

* * * * *

(c) *Applications for approval of an alternative standard.* An application for approval of an alternative standard or for an amendment or extension of the alternative standard shall be submitted in an original and two copies to the Food and Drug Administration, Center for Devices and Radiological Health, Director, Division of Mammography Quality Standards, 10903 New Hampshire Ave., Bldg. 66, Rm. 3621, Silver Spring, MD 20993–0002. The application for approval of an alternative standard shall include the following information:

* * * * *

■ 38. In § 900.21, revise paragraph (b)(1) to read as follows:

§ 900.21 Application for approval as a certification agency.

* * * * *

(b) * * * (1) An applicant seeking FDA approval as a certification agency shall inform the Food and Drug Administration, Center for Devices and Radiological Health, Director, Division of Mammography Quality Standards, Attn: Program Management Branch, 10903 New Hampshire Ave., Bldg. 66, Rm. 3621, Silver Spring, MD 20993–0002, in writing, of its desire to be approved as a certification agency.

* * * * *

PART 1002—RECORDS AND REPORTS

■ 39. The authority citation for part 1002 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 360hh–360ss, 371, 374.

■ 40. In § 1002.50, revise paragraph (c)(3) to read as follows:

§ 1002.50 Special exemptions.

* * * * *

(c) * * *

(3) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall be available upon request from the Food and Drug Administration, Center for Devices and Radiological Health, Division of Mammography Quality Standards, 10903 New Hampshire Ave., Bldg. 66, Rm. 3621, Silver Spring, MD 20993–0002.

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Dated: March 23, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06354 Filed 4–1–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862 and 866

[Docket No. FDA–2020–N–0011]

Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or Agency) is amending certain medical device regulations to accurately reflect the devices exempted from premarket notification (510(k)) as indicated in the lists published on April 13, 2017, and July 11, 2017. FDA published a final amendment, final order in the **Federal Register** of December 30, 2019 (''Final Order'') codifying the two **Federal Register** notices. The present revisions are necessary to correct editorial errors to ensure that the codified is consistent with the exemptions in the **Federal Register** notices. The rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations.

DATES: This rule is effective April 1, 2020.

FOR FURTHER INFORMATION CONTACT: Ryan Lubert, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3574, Silver Spring, MD 20993–0002, 240–402–6357.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 510(l)(2) and 510(m)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(l)(2) and 360(m)(1)(A)), FDA issued two separate notices of final determination exempting a list of class I and II devices from section 510(k) of the FD&C Act, respectively, subject to certain limitations published in the **Federal Register** April 13, 2017 (82 FR 17841) and July 11, 2017 (82 FR 31976). The devices included in these lists were exempt upon publication of the final determination notices in the **Federal Register** notices (see sections 510(l)(2)(A) and 510(m)(3) of the FD&C Act). On December 30, 2019 (84 FR 71794), FDA issued an amendment, final order, which amended the codified for the classification regulations implicated in the **Federal Register** notices to reflect the exemptions and limitations on exemptions in those notices. This Final Order incorrectly amended the codified for three device types such that the exemption in the current codified is inconsistent with the scope of the device exemptions described in the **Federal Register** notices. Specifically, for the three implicated device types, FDA indicated in the **Federal Register** notices that a device with a particular intended use was exempt from the premarket notification requirements in section 510(k) of the FD&C Act; however, the codified currently indicates that the entire device type is exempt from section 510(k) of the FD&C Act, which is not the case.

As such, FDA is amending the codified for §§ 862.1345, 862.1775, and 866.2900 (21 CFR 862.1345, 862.1775, and 866.2900) to be consistent with the exemptions as stated in the **Federal Register** notices. These amendments are not substantive changes because the **Federal Register** notices exempted the affected devices from the section 510(k) of the FD&C Act, but are intended to correct the codified and to clarify which devices under those classification regulations are exempt from the premarket notification requirements in section 510(k) of the FD&C Act and which device types remain subject to such requirements.

II. Description of the Technical Amendments

The regulations specified in this rule have been revised to correct and clarify the codified language of the regulations specified in this technical amendment, specifically §§ 862.1345, 862.1775, and 866.2900, to be consistent with the exemptions as stated in the **Federal Register** notices. FDA is making no substantive changes to the following regulations:

1. FDA is revising § 862.1345(b) by replacing ''The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9''