

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2019–24–15 The Boeing Company:
Amendment 39–21004; Docket No. FAA–2019–0980; Product Identifier 2019–NM–180–AD.

(a) Effective Date

This AD is effective January 14, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 737–900ER series airplanes, certificated in any category, as identified in Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings.

(e) Unsafe Condition

This AD was prompted by a report of nonconforming head strike pads on the mid exit doors. The FAA is issuing this AD to address nonconforming head strike pads which could result in injury to passengers in an otherwise survivable emergency landing and potentially block passenger egress.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the “Compliance” paragraph of Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Special Attention Service Bulletin 737–25–1831, dated September 24, 2019, which is referred to in Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019.

(h) Exceptions to Service Information Specifications

Where Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019, uses the phrase “the original issue date of the Requirements Bulletin 737–25–1831 RB,” this AD requires using “the effective date of this AD.”

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with

14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

For more information about this AD, contact Allie Buss, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3564; email: allison.buss@faa.gov.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Special Attention Requirements Bulletin 737–25–1831 RB, dated September 24, 2019.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminister Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; phone: 562–797–1717; internet: <https://www.myboeingfleet.com>.

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov, or go to: <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Des Moines, Washington, on December 9, 2019.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2019–28070 Filed 12–27–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

21 CFR Parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892

[Docket Nos. FDA–2017–N–1129 and FDA–2017–N–1610]

Medical Devices; Exemptions From Premarket Notification for Class I and Class II Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) identified a list of class I devices and class II devices that are now exempt from premarket notification requirements, subject to certain limitations. FDA published the lists of final determinations in accordance with procedures established by the 21st Century Cures Act (Cures Act). Although each classification regulation for each such type of device shall be deemed amended to incorporate such exemption, we are publishing this final order to amend the codified language for each listed class I and class II device’s classification regulation to reflect the final determinations. FDA’s action decreases regulatory burden on the medical device industry and eliminates private costs and expenditures required to comply with certain Federal regulations.

DATES: This order is effective December 30, 2019.

FOR FURTHER INFORMATION CONTACT: Karen Fikes, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5502, Silver Spring, MD 20993, 301–796–9603, email: karen.fikes@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

The Cures Act (Pub. L. 114–255) was signed into law on December 13, 2016. Under the Cures Act, section 3054 amended section 510(l) and (m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360(l) and (m)). As amended, section 510(l)(2) of the FD&C Act requires FDA to identify through publication in the **Federal Register**, any type of class I device that the Agency determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness.

FDA shall publish this determination within 120 days of the date of enactment of the Cures Act and at least once every 5 years thereafter, as FDA determines appropriate. Further, section 510(l)(2) provides that upon the date of publication of the Agency's determination in the **Federal Register**, a 510(k) will no longer be required for these devices and the classification regulation applicable to each such type of device shall be deemed amended to incorporate such exemption.

As amended, section 510(m)(1)(A) of the FD&C Act provides that, within 90 days after enactment of the Cures Act and at least once every 5 years thereafter, FDA shall publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. This notice shall provide at least a 60-day comment period. Within 210 days of enactment of the Cures Act, FDA shall publish in the **Federal Register** a list representing its final determination regarding exemption of devices that were contained in the proposed list published under 510(m)(1)(A) of the FD&C Act. Further, section 510(m)(3) of the FD&C Act provides that upon the date of publication of the final list in the **Federal Register**, a 510(k) will no longer be required for these devices and the classification regulation applicable to each such device shall be deemed amended to incorporate such exemption.

In the **Federal Register** of April 13, 2017 (82 FR 17841), in accordance with the amendments to 510(l)(2), FDA issued a notice of final determination to exempt a list of class I devices from premarket notification requirements under section 510(k) of the FD&C Act, subject to certain limitations. In the **Federal Register** of March 14, 2017 (82 FR 13609), in accordance with the amendments to 510(m)(1)(A), FDA issued a notice proposing to exempt a list of class II devices from premarket notification requirements under section 510(k) of the FD&C Act, subject to certain limitations. After a 60-day comment period, in the **Federal Register** of July 11, 2017 (82 FR 31976), FDA issued a notice of final determination to exempt class II devices provided in the proposed list. Through this action, FDA is now amending the codified language for each listed classification regulation to reflect final determinations for these class I and class II exemptions.¹

¹ FDA notes that the "ACTION" caption for this final order is styled as "Final amendment; final

Following publication of the notices, FDA determined that it is unnecessary to update three classification regulations (21 CFR 872.4565, 21 CFR 878.4014, and 21 CFR 880.6320) included in the class I notice, 82 FR 17841. Five product codes corresponding to these three classification regulations (EGI and EIB (21 CFR 872.4565), OVR (21 CFR 878.4014), KZF and PEQ (21 CFR 880.6320)) were identified for exemption in 82 FR 17841; however, the corresponding classification regulations were already class I, exempt from premarket notification procedures in subpart E of part 807 (21 CFR part 807, subpart E) subject to the limitations in the corresponding ".9" regulations (*i.e.*, 21 CFR 872.9, 21 CFR 878.9 or 21 CFR 880.9); and, therefore, no revisions to the codified are necessary. Additionally, we determined that it is unnecessary to update 21 CFR 876.5820 included in the class II notice, 82 FR 13609. The product code within this classification regulation (FKI) was identified for exemption in 82 FR 13609. However, this device type is specifically identified within the class I paragraph of this classification regulation (21 CFR 876.5820(b)(2)) and already exempt from premarket notification procedures in subpart E of part 807 subject to the limitations in 21 CFR 876.9. Therefore, no revisions to the codified are necessary.

We are also making a revision to correct a misidentified classification regulation in 82 FR 31976. The notice incorrectly listed the classification regulation 21 CFR 868.1400 "Carbon dioxide gas analyzer" as corresponding with product code LLK; however, the correct classification regulation associated with product code LLK is 21 CFR 880.5780 "Medical Support Stocking". Therefore, 21 CFR 868.1400 remains unchanged, and 21 CFR 880.5780(a)(2) is revised to reflect the exemption.

We are revising the name of one classification regulation, currently entitled "Urological clamp for males", in response to FDA's exemption in 82 FR 17841. Part 876.5160 is currently entitled "Urological clamp for males," which was previously exempt from premarket notification procedures ". . . Except when intended for internal use or use on females . . .". In 82 FR 17841,

order," rather than "Final order." Beginning in December 2019, this editorial change was made to indicate that the document "amends" the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.

we exempted product code MNG, "External Urethral Occluder, Urinary Incontinence-Control, Female" and removed the current limitation language regarding "use on females." Therefore, FDA is revising the name of the classification regulation to read "Urological clamp" to ensure clarity.

II. Criteria for Exemption

As amended by the Cures Act, section 510(l) now has two provisions, 510(l)(1) and (2). Under 510(l)(1), a class I device is exempt from the premarket notification requirements under section 510(k) of the FD&C Act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. Based on these criteria, FDA evaluated all class I devices to determine which device types should be exempt from premarket notification requirements.

For class II devices, there are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance we issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions From Premarket Notification, Guidance for Industry and CDRH Staff".²

III. Limitations on Exemptions

Although FDA exempted the types of class I and class II devices from the premarket notification requirements under section 510(k) of the FD&C Act in accordance with the provisions under 510(l) and (m), an exemption from the requirement of premarket notification does not mean the device is exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation. FDA's determination that premarket notification is unnecessary to provide a reasonable assurance of safety and effectiveness is based, in part, on the assurance of safety and effectiveness that other regulatory controls, such as current good manufacturing practice requirements, provide.

In addition to being subject to the general limitations to the exemptions found in 21 CFR 862.9 to 892.9, FDA has also partially limited some exemptions from premarket notification requirements to specific devices within

² Available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/procedures-class-ii-device-exemptions-premarket-notification-guidance-industry-and-cdrh-staff>.

the listed device type. In such situations where a partial exemption limitation has been identified, FDA has determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for these devices.

IV. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) 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.

V. Paperwork Reduction Act of 1995

This final order refers to previously approved FDA collections of information. 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. 3501–3521). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR parts 801 and 809, regarding labeling, have been approved under OMB control number 0910–0485; and the collections of information in 21 CFR part 820, regarding quality system regulation, have been approved under OMB control number 0910–0073.

List of Subjects

21 CFR Parts 862, 868, 870, 872, 874, 876, 878, 880, 882, 884, 888, and 890

Medical devices.

21 CFR Part 864

Blood, Medical devices, Packaging and Containers.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

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 parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892 are amended as follow:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

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

■ 2. In § 862.1020, revise paragraph (b) to read as follows:

§ 862.1020 Acid phosphatase (total or prostatic) test system.

* * * * *

(b) *Classification.* Class II (special controls). 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.

■ 3. In § 862.1090, revise paragraph (b) to read as follows:

§ 862.1090 Angiotensin converting enzyme (A.C.E.) test system.

* * * * *

(b) *Classification.* Class II (special controls). 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.

■ 4. In § 862.1100, revise paragraph (b) to read as follows:

§ 862.1100 Aspartate amino transferase (AST/SGOT) test system.

* * * * *

(b) *Classification.* Class II (special controls). 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.

■ 5. In § 862.1150, revise paragraph (b) to read as follows:

§ 862.1150 Calibrator.

* * * * *

(b) *Classification.* Class II (special controls). 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.

■ 6. In § 862.1345, revise paragraph (b) to read as follows:

§ 862.1345 Glucose test system.

* * * * *

(b) *Classification.* Class II (special controls). 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.

■ 7. In § 862.1350, revise paragraph (b) introductory text to read as follows:

§ 862.1350 Continuous glucose monitor secondary display.

* * * * *

(b) *Classification.* Class II (special controls). 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. The special controls for this device are:

* * * * *

■ 8. In § 862.1410, revise paragraph (b) to read as follows:

§ 862.1410 Iron (non-heme) test system.

* * * * *

(b) *Classification.* Class I (general controls). 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.

■ 9. In § 862.1415, revise paragraph (b) to read as follows:

§ 862.1415 Iron-binding capacity test system.

* * * * *

(b) *Classification.* Class I (general controls). 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.

■ 10. In § 862.1445, revise paragraph (b) to read as follows:

§ 862.1445 Lactate dehydrogenase isoenzymes test system.

* * * * *

(b) *Classification.* Class II (special controls). 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.

■ 11. In § 862.1509, revise paragraph (b) to read as follows:

§ 862.1509 Methylmalonic acid (nonquantitative) test system.

* * * * *

(b) *Classification.* Class II (special controls). 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.

■ 12. In § 862.1580, revise paragraph (b) to read as follows:

§ 862.1580 Phosphorous (inorganic) test system.

* * * * *

(b) *Classification.* Class I (general controls). 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.

■ 13. In § 862.1660, revise paragraph (b) to read as follows:

§ 862.1660 Quality control material (assayed and unassayed).

* * * * *

(b) *Classification.* Class I (general controls). Except when intended for use in donor screening tests, quality control materials (assayed and unassayed) are

exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9.

■ 14. In § 862.1685, revise paragraph (b) as follows:

§ 862.1685 Thyroxine-binding globulin test system.

* * * * *

(b) *Classification.* Class II (special controls). 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.

■ 15. In § 862.1700, revise paragraph (b) as follows:

§ 862.1700 Total thyroxine test system.

* * * * *

(b) *Classification.* Class II (special controls). 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.

■ 16. In § 862.1775, revise paragraph (b) to read as follows:

§ 862.1775 Uric acid test system.

* * * * *

(b) *Classification.* Class I (general controls). 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.

■ 17. In § 862.2265, revise paragraph (b) introductory text to read as follows:

§ 862.2265 High throughput genomic sequence analyzer for clinical use.

* * * * *

(b) *Classification.* Class II (special controls). 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. The special controls for this device are:

* * * * *

■ 18. In § 862.2570, revise paragraph (b) to read as follows:

§ 862.2570 Instrumentation for clinical multiplex test systems.

* * * * *

(b) *Classification.* Class II (special controls). 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. The special control is FDA's guidance document entitled "Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems." See § 862.1(d) for the availability of this guidance document.

■ 19. In § 862.3050, revise paragraph (b) to read as follows:

§ 862.3050 Breath-alcohol test system.

* * * * *

(b) *Classification.* Class I (general controls). 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.

■ 20. In § 862.3100, revise paragraph (b) to read as follows:

§ 862.3100 Amphetamine test system.

* * * * *

(b) *Classification.* Class II (special controls). An amphetamine test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 21. In § 862.3150, revise paragraph (b) to read as follows:

§ 862.3150 Barbiturate test system.

* * * * *

(b) *Classification.* Class II (special controls). A barbiturate test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 22. In § 862.3170, revise paragraph (b) to read as follows:

§ 862.3170 Benzodiazepine test system.

* * * * *

(b) *Classification.* Class II (special controls). A benzodiazepine test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug

testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 23. In § 862.3200, revise paragraph (b) to read as follows:

§ 862.3200 Clinical toxicology calibrator.

* * * * *

(b) *Classification.* Class II (special controls). 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.

■ 24. In § 862.3220, revise paragraph (b) to read as follows:

§ 862.3220 Carbon monoxide test system.

* * * * *

(b) *Classification.* Class I (general controls). 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.

■ 25. In § 862.3240, revise paragraph (b) to read as follows:

§ 862.3240 Cholinesterase test system.

* * * * *

(b) *Classification.* Class I (general controls). 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.

■ 26. In § 862.3250, revise paragraph (b) to read as follows:

§ 862.3250 Cocaine and cocaine metabolite test system.

* * * * *

(b) *Classification.* Class II (special controls). A cocaine and cocaine metabolite test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g.,

programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 27. In § 862.3270, revise paragraph (b) to read as follows:

§ 862.3270 Codeine test system.

* * * * *

(b) *Classification.* Class II (special controls). A codeine test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 28. In § 862.3280, revise paragraph (b) to read as follows:

§ 862.3280 Clinical toxicology control material.

* * * * *

(b) *Classification.* Class I (general controls). 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.

■ 29. In § 862.3580, revise paragraph (b) to read as follows:

§ 862.3580 Lysergic acid diethylamide (LSD) test system.

* * * * *

(b) *Classification.* Class II (special controls). A lysergic acid diethylamide (LSD) test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the

Department of Transportation (DOT), and the U.S. military).

■ 30. In § 862.3610, revise paragraph (b) to read as follows:

§ 862.3610 Methamphetamine test system.

* * * * *

(b) *Classification.* Class II (special controls). A methamphetamine test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 31. In § 862.3620, revise paragraph (b) to read as follows:

§ 862.3620 Methadone test system.

* * * * *

(b) *Classification.* Class II (special controls). A methadone test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 32. In § 862.3630, revise paragraph (b) to read as follows:

§ 862.3630 Methaqualone test system.

* * * * *

(b) *Classification.* Class II (special controls). A methaqualone test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 33. In § 862.3640, revise paragraph (b) to read as follows:

§ 862.3640 Morphine test system.

* * * * *

(b) *Classification.* Class II (special controls). A morphine test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 34. In § 862.3650, revise paragraph (b) to read as follows:

§ 862.3650 Opiate test system.

* * * * *

(b) *Classification.* Class II (special controls). An opiate test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 35. In § 862.3700, revise paragraph (b) to read as follows:

§ 862.3700 Propoxyphene test system.

* * * * *

(b) *Classification*. Class II (special controls). A propoxyphene test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 36. In § 862.3870, revise paragraph (b) to read as follows:

§ 862.3870 Cannabinoid test system.

* * * * *

(b) *Classification*. Class II (special controls). A cannabinoid test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

■ 37. In § 862.3910, revise paragraph (b) to read as follows:

§ 862.3910 Tricyclic antidepressant drugs test system.

* * * * *

(b) *Classification*. Class II (special controls). A tricyclic antidepressant drugs test system is not exempt if it is intended for any use other than employment or insurance testing or is intended for Federal drug testing programs. 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, provided the test system is intended for employment and insurance testing and includes a statement in the labeling that the device is intended solely for use in employment and insurance testing, and does not include devices intended for

Federal drug testing programs (e.g., programs run by the Substance Abuse and Mental Health Services Administration (SAMHSA), the Department of Transportation (DOT), and the U.S. military).

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 38. The authority citation for part 864 continues to read as follows:

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

■ 39. In § 864.5400, revise paragraph (b) to read as follows:

§ 864.5400 Coagulation instrument.

* * * * *

(b) *Classification*. Class II (special controls). A fibrometer or coagulation timer intended for use with a coagulation instrument is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 40. In § 864.5425, revise paragraph (b) to read as follows:

§ 864.5425 Multipurpose system for in vitro coagulation studies.

* * * * *

(b) *Classification*. Class II (special controls). A control intended for use with a multipurpose system for in vitro coagulation studies is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 41. In § 864.6550, revise paragraph (b) to read as follows:

§ 864.6550 Occult blood test.

* * * * *

(b) *Classification*. Class II (special controls). A control intended for use with an occult blood test is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 42. In § 864.7040, revise paragraph (b) to read as follows:

§ 864.7040 Adenosine triphosphate release assay.

* * * * *

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 43. In § 864.7275, revise paragraph (b) to read as follows:

§ 864.7275 Euglobulin lysis time tests.

* * * * *

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 44. In § 864.7300, revise paragraph (b) to read as follows:

§ 864.7300 Fibrin monomer paracoagulation test.

* * * * *

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. The special control for this device is FDA's "In Vitro Diagnostic Fibrin Monomer Paracoagulation Test." See § 864.1(d) for information on obtaining this document.

■ 45. In § 864.7340, revise paragraph (b) to read as follows:

§ 864.7340 Fibrinogen determination system.

* * * * *

(b) *Classification*. Class II (special controls). A control or fibrinogen standard intended for use with a fibrinogen determination system is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 46. In § 864.7375, revise paragraph (b) to read as follows:

§ 864.7375 Glutathione reductase assay.

* * * * *

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 47. In § 864.7415, revise paragraph (b) to read as follows:

§ 864.7415 Abnormal hemoglobin assay.

* * * * *

(b) *Classification*. Class II (special controls). A control intended for use with an abnormal hemoglobin assay is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 48. In § 864.7455, revise paragraph (b) to read as follows:

§ 864.7455 Fetal hemoglobin assay.

* * * * *

(b) *Classification*. Class II (special controls). A fetal hemoglobin stain intended for use with a fetal hemoglobin assay is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 49. In § 864.7500, revise paragraph (b) to read as follows:

§ 864.7500 Whole blood hemoglobin assays.

* * * * *

(b) *Classification.* Class II (special controls). An acid hematin intended for use with whole blood hemoglobin assays is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 50. In § 864.7720, revise paragraph (b) to read as follows:

§ 864.7720 Prothrombin consumption test.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 51. In § 864.7735, revise paragraph (b) to read as follows:

§ 864.7735 Prothrombin-proconvertin test and thrombotest.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 52. In § 864.8150, revise paragraph (b) to read as follows:

§ 864.8150 Calibrator for cell indices.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 53. In § 864.8165, revise paragraph (b) to read as follows:

§ 864.8165 Calibrator for hemoglobin or hematocrit measurement.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 54. In § 864.8175, revise paragraph (b) to read as follows:

§ 864.8175 Calibrator for platelet counting.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 55. In § 864.8185, revise paragraph (b) to read as follows:

§ 864.8185 Calibrator for red cell and white cell counting.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 56. In § 864.8625, revise paragraph (b) to read as follows:

§ 864.8625 Hematology quality control mixture.

* * * * *

(b) *Classification.* Class II (special controls). Except when intended for use in blood components, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

■ 57. In § 864.9400, revise paragraph (b) to read as follows:

§ 864.9400 Stabilized enzyme solution.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 58. The authority citation for part 866 continues to read as follows:

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

■ 59. In § 866.2900, revise paragraph (b) to read as follows:

§ 866.2900 Microbiological specimen collection and transport device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

■ 60. In § 866.3395, revise paragraph (b) to read as follows:

§ 866.3395 Norovirus serological reagents.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The special control is FDA's guidance

document entitled "Class II Special Controls Guidance Document: Norovirus Serological Reagents." See § 866.1(e) for the availability of this guidance document.

■ 61. In § 866.5210, revise paragraph (b) to read as follows:

§ 866.5210 Ceruloplasmin immunological test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

■ 62. In § 866.5470, revise paragraph (b) to read as follows:

§ 866.5470 Hemoglobin immunological test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

■ 63. In § 866.5620, revise paragraph (b) to read as follows:

§ 866.5620 Alpha-2-macroglobulin immunological test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

■ 64. In § 866.5630, revise paragraph (b) to read as follows:

§ 866.5630 Beta-2-microglobulin immunological test system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

■ 65. In § 866.5750, revise paragraph (b) to read as follows:

§ 866.5750 Radioallergosorbent (RAST) immunological test system.

* * * * *

(b) *Classification.* Class II (special controls). The device, when intended to detect any of the allergens included in Table 1 in this paragraph, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9.

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGIOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS

| Allergen code | Allergen product | Source (taxonomical name) |
|----------------------|-------------------------------------------|----------------------------------------------------------------------------------|
| Grass Pollens | | |
| g1 | Sweet vernal grass | <i>Anthoxanthum odoratum</i> . |
| g3 | Cocksfoot grass, Orchard grass | <i>Dactylis glomerata</i> . |
| g4 | Meadow fescue | <i>Festuca elatior</i> . |
| g5 | Rye-grass (perennial rye grass) | <i>Lolium perenne</i> . |
| g7 | Common reed (common reed grass) | <i>Phragmites communis</i> . |
| g8 | Meadow grass, Kentucky blue (June grass) | <i>Poa pratensis</i> . |
| g9 | Redtop, Bentgrass | <i>Agrostis stolonifera</i> , <i>Agrostis gigantea</i> (<i>Agrostis alba</i>). |
| g11 | Brome grass | <i>Bromus inermis</i> . |
| g12 | Cultivated rye (cultivated rye grass) | <i>Secale cereale</i> . |
| g13 | Velvet grass | <i>Holcus lanatus</i> . |
| g14 | Cultivated oat (cultivated oat grass) | <i>Avena sativa</i> . |
| g15 | Cultivated wheat (cultivated wheat grass) | <i>Triticum aestivum</i> (<i>Triticum</i> spp.). |
| g16 | Meadow foxtail (meadow foxtail grass) | <i>Alopecurus pratensis</i> . |
| g17 | Bahia grass | <i>Paspalum notatum</i> . |
| g24 | Wheat grass, Western | <i>Agropyron smithii</i> (<i>Elymus smithii</i>). |
| g30 | Bluegrass, annual | <i>Poa annua</i> . |
| g70 | Wild rye grass | <i>Elymus triticoides</i> <i>Elymus condensatus</i> . |
| g71 | Canary grass | <i>Phalaris arundinacea</i> . |
| g201 | Barley, cultivated | <i>Hordeum vulgare</i> . |
| g202 | Maize, corn (cultivated corn) | <i>Zea mays</i> . |
| g203 | Salt grass | <i>Distichlis spicata</i> . |
| g204 | False oat-grass | <i>Arrhenatherum elatius</i> . |
| g216 | Cyn d 1 | <i>Cynodon dactylon</i> . |
| g701 | Phl p 1.0102, Phl p 5.0101 | <i>Phleum pratense</i> . |
| g702 | Phl p 7.0101 | <i>Phleum pratense</i> . |
| g703 | Phl p 12.0101 | <i>Phleum pratense</i> . |
| Weed Pollens | | |
| w2 | Western ragweed | <i>Ambrosia psilostachya</i> . |
| w4 | False ragweed | <i>Ambrosia acanthicarpa</i> (<i>Franseria acanthicarpa</i>). |
| w5 | Wormwood | <i>Artemisia absinthium</i> <i>Artemisia annua</i> . |
| w6 | Mugwort | <i>Artemisia vulgaris</i> . |
| w7 | Marguerite, ox-eye daisy | <i>Chrysanthemum leucanthemum</i> . |
| w8 | Dandelion | <i>Taraxacum vulgare</i> , <i>Taraxacum officinale</i> . |
| w9 | Plantain (English), Ribwort | <i>Plantago lanceolata</i> . |
| w10 | Goosefoot, lamb's quarters | <i>Chenopodium album</i> . |
| w11 | Saltwort (prickly), Russian thistle | <i>Salsola kali</i> (<i>Salsola pestifer</i>). |
| w12 | Goldenrod | <i>Solidago virgaurea</i> (<i>Solidago</i> spp.). |
| w13 | Cocklebur, common | <i>Xanthium commune</i> . |
| w14 | Common pigweed (rough pigweed) | <i>Amaranthus retroflexus</i> . |
| w15 | Scale, Lenscale | <i>Atriplex lentiformis</i> . |
| w16 | Rough marsh elder | <i>Iva ciliate</i> , <i>Iva annua</i> . |
| w17 | Firebush (Kochia) | <i>Kochia scoparia</i> . |
| w18 | Sheep sorrel | <i>Rumex acetosella</i> . |
| w19 | Wall pellitory | <i>Parietaria officinalis</i> . |
| w20 | Nettle (Common stinging nettle) | <i>Urtica dioica</i> . |
| w21 | Wall pellitory | <i>Parietaria judaica</i> . |
| w22 | Japanese hop (careless weed) | <i>Humulus japonicas</i> (<i>Humulus scandens</i>). |
| w23 | Yellow dock, Yellow dockweed | <i>Rumex crispus</i> . |
| w24 | Spiny pigweed | <i>Amaranthus spinosus</i> . |
| w27 | Carnation | <i>Dianthus</i> spp. |
| w28 | Rose | <i>Rosa rugosa</i> . |
| w33 | Clover | <i>Trifolium pratense</i> . |
| w35 | Mexican tea | <i>Chenopodium ambrosioides</i> . |
| w36 | Rabbit bush | <i>Ambrosia deltoidea</i> (<i>Franseria deltoidea</i>). |
| w37 | Salt bush, annual | <i>Atriplex wrightii</i> . |
| w39 | Water hemp, Western | <i>Amaranthus rudis</i> (<i>Acnida tamariscina</i>). |
| w41 | Burrobrush | <i>Hymenoclea salsola</i> . |
| w42 | Poverty weed | <i>Baccharis neglecta</i> . |
| w43 | Common sagebrush | <i>Artemisia tridentata</i> . |
| w45 | Alfalfa | <i>Medicago sativa</i> . |
| w46 | Dog fennel | <i>Eupatorium capillifolium</i> . |
| w53 | Geranium | <i>Geranium</i> spp. |
| w67 | Groundsel bush | <i>Baccharis halimifolia</i> . |
| w69 | Iodine bush | <i>Allenrolfea occidentalis</i> . |
| w70 | Ragweed, slender | <i>Ambrosia confertiflora</i> . |
| w75 | Wing scale (wingscale) | <i>Atriplex canescens</i> . |

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

| Allergen code | Allergen product | Source (taxonomical name) |
|---------------------|--------------------------------------------------|-------------------------------------------------------------------|
| w82 | Careless weed | <i>Amaranthus palmeri</i> , <i>Amaranthus hybridus</i> . |
| w90 | Japanese hop | <i>Humulus japonicas</i> (<i>Humulus scandens</i>). |
| w203 | Rape (rape pollen) | <i>Brassica napus</i> . |
| w204 | Sunflower | <i>Helianthus annuus</i> . |
| w206 | Camomile | <i>Matricaria chamomilla</i> . |
| w207 | Lupin | <i>Lupinus</i> spp. |
| w210 | Sugar-beet | <i>Beta vulgaris</i> . |
| w211 | Par j 2.0101 | <i>Parietaria judaica</i> . |
| w231 | Art v 1 | <i>Artemisia vulgaris</i> (Mugwort). |
| w232 | Sal k 1 | <i>Salsola kali</i> . |
| w233 | Art v 3 | <i>Artemisa vulgaris</i> (LTP, Mugwort). |
| w234 | Pla l 1 | <i>Plantago lanceolata</i> . |
| w235 | Che a 1.0101 | <i>Chenopodium album</i> . |
| w236 | Mer a 1.0101 | <i>Mercurialis annua</i> . |
| a753 | Art v 1 | <i>Artemisia vulgaris</i> (Mugwort weed). |
| Tree Pollens | | |
| t1 | Box-elder (Maple) | <i>Acer negundo</i> , <i>Acer saccharum</i> . |
| t2 | Gray alder, speckled alder (alder) | <i>Alnus incana</i> . |
| t4 | Hazel, hazelnut | <i>Corylus avellana</i> , <i>Corylus americana</i> . |
| t5 | American beech (beech) | <i>Fagus grandifolia</i> (<i>Fagus americana</i>). |
| t6 | Mountain juniper, Mountain cedar | <i>Juniperus ashei</i> (<i>Juniperus sabinoides</i>). |
| t8 | Elm | <i>Ulmus americana</i> . |
| t9 | Olive | <i>Olea europaea</i> . |
| t10 | Walnut | <i>Juglans californica</i> , <i>Juglans nigra</i> . |
| t11 | Maple leaf sycamore, London plane, Plane tree | <i>Platanus acerifolia</i> . |
| t61 | Sycamore | <i>Platanus occidentalis</i> . |
| t12 | Willow | <i>Salix caprea</i> , <i>Salix nigra</i> . |
| t14 | Cottonwood (Eastern Cottonwood/Black Cottonwood) | <i>Populus deltoides</i> . |
| t15 | White ash | <i>Fraxinus americana</i> . |
| t16 | White pine | <i>Pinus strobus</i> . |
| t18 | Eucalyptus, gum-tree | <i>Eucalyptus globulus</i> (<i>Eucalyptus</i> spp.). |
| t19/t26 | Acacia | <i>Acacia longifolia</i> (<i>Acacia</i> spp.). |
| t20 | Mesquite | <i>Prosopis glandulosa</i> / <i>Prosopis juliflora</i> . |
| t21 | Melaleuca, cajeput tree | <i>Melaleuca quinquenervia</i> (<i>Melaleuca leucadendron</i>). |
| t22 | Pecan, hickory | <i>Carya illinoensis</i> (<i>Carya pecan</i>). |
| t23 | Italian/Mediterranean/funeral cypress | <i>Cupressus sempervirens</i> . |
| t24 | Japanese cypress | <i>Chamaecyparis obtusa</i> (<i>Chamaecyparis</i> spp.). |
| t25 | Ash | <i>Fraxinus excelsior</i> . |
| t27 | Maple, red | <i>Acer rubrum</i> . |
| t29 | Acacia | <i>Acacia</i> spp. |
| t30 | Birch, white | <i>Betula populifolia</i> . |
| t32 | Willow, black | <i>Salix nigra</i> . |
| t33 | Ash, Arizona | <i>Fraxinus velutina</i> . |
| t35 | Cedar, salt | <i>Tamarix gallica</i> . |
| t37 | Bald cypress (white bald cypress) | <i>Taxodium distichum</i> . |
| t38 | Elm, Chinese/Siberian | <i>Ulmus pumila</i> . |
| t40 | Hazelnut tree | <i>Corylus americana</i> . |
| t41 | White hickory | <i>Carya alba</i> (<i>Carya tomentosa</i>). |
| t42 | Oak, red | <i>Quercus rubra</i> . |
| t43 | Loblolly pine | <i>Pinus taeda</i> . |
| t44 | Hackberry | <i>Celtis occidentalis</i> . |
| t45 | Cedar elm | <i>Ulmus crassifolia</i> . |
| t47 | Juniper, one seed | <i>Juniperus monosperma</i> . |
| t48 | Pine, lodgepole | <i>Pinus contorta</i> . |
| t49 | Pine, ponderosa | <i>Pinus ponderosa</i> . |
| t50 | Beech, European | <i>Fagus sylvatica</i> . |
| t51 | Tree of Heaven | <i>Ailanthus altissima</i> . |
| t52 | Western white pine | <i>Pinus monticola</i> . |
| t54 | Russian olive | <i>Elaeagnus angustifolia</i> . |
| t55 | Scotch broom | <i>Cytisus scoparius</i> . |
| t56 | Bayberry | <i>Myrica cerifera</i> . |
| t57 | Red cedar | <i>Juniperus virginiana</i> . |
| t60 | Western juniper | <i>Juniperus occidentalis</i> . |
| t61 | Sycamore | <i>Platanus occidentalis</i> . |
| t70 | Mulberry (white mulberry) | <i>Morus alba</i> . |
| t71 | Red mulberry | <i>Morus rubra</i> . |
| t72 | Queen palm | <i>Arecastrum romanzoffianon</i> . |
| t73 | Australian pine | <i>Casuarina equisetifolia</i> . |

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

| Allergen code | Allergen product | Source (taxonomical name) |
|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|
| t77 | Oak mix (red, white, black) | <i>Quercus</i> spp. |
| t80 | Japanese cypress | <i>Chamaecyparis obtusa</i> . |
| t81 | Japanese alder | <i>Alnus japonica</i> . |
| t83 | Mango tree | <i>Mangifera indica</i> . |
| t90 | Walnut, black | <i>Juglans nigra</i> . |
| t96 | Poplar, white (poplar) | <i>Populus alba</i> . |
| t103/t218 | Virginia live oak (live oak) | <i>Quercus virginiana</i> . |
| t105 | Pepper tree | <i>Schinus molle</i> . |
| t110 | Orange tree | <i>Citrus sinensis</i> . |
| t201 | Spruce, Norway spruce | <i>Picea abies</i> (<i>Picea excelsa</i>). |
| t202 | Alder, smooth | <i>Alnus incana</i> spp. <i>Rugosa</i> (<i>Alnus rugosa</i>). |
| t203 | Horse chestnut | <i>Aesculus hippocastanum</i> . |
| t205 | Elder | <i>Sambucus nigra</i> . |
| t206 | Chestnut | <i>Castanea sativa</i> . |
| t207 | Douglas fir | <i>Pseudotsuga menziesii</i> (<i>Pseudotsuga taxifolia</i>). |
| t208 | Linden | <i>Tilia cordata</i> . |
| t209 | Horn beam | <i>Carpinus betulus</i> . |
| t210 | Privet | <i>Ligustrum vulgare</i> . |
| t211 | Sweet gum | <i>Liquidambar styraciflua</i> . |
| t212 | Cedar | <i>Libocedrus decurrens</i> . |
| t213 | Pine | <i>Pinus radiata</i> . |
| t214 | Date palm | <i>Phoenix canariensis</i> . |
| t215 | Lilac | <i>Syringa vulgaris</i> . |
| t217 | Pepper tree | <i>Schinus molle</i> . |
| t217 | Red alder | <i>Alnus rubra</i> . |
| t218 | Virginia live oak | <i>Quercus virginiana</i> . |
| t218 | Bayberry (bayberry/sweet gale) | <i>Myrica gale</i> . |
| t219 | Palo verde | <i>Cercidium floridum</i> . |
| t219 | Red cedar | <i>Juniperus virginiana</i> . |
| t220 | Bet v 4 | <i>Betula verrucosa</i> (Birch). |
| t221 | Bet v 2.0101, Bet v 4 | <i>Betula verrucosa</i> (Birch). |
| t222 | Cypress (Arizona cypress) | <i>Cupressus arizonica</i> . |
| t223 | Oil palm | <i>Elaeis guineensis</i> . |
| t224 | Ole e 1 | <i>Olea europaea</i> . |
| t225 | Bet v 6 | <i>Betula verrucosa</i> (Birch). |
| t226 | Cup a 1 | <i>Cupressus arizonica</i> . |
| t227 | Ole e 7 | <i>Olea Europaea</i> . |
| t228 | Aspen, quaking | <i>Populus tremuloides</i> . |
| t229 | Eastern hemlock | <i>Tsuga canadensis</i> . |
| t230 | Redwood (sequoia) | <i>Sequoia sempervirens</i> . |
| t232 | Pussy willow | <i>Salix discolor</i> . |
| t240 | Ole e 9.0101 | <i>Olea Europaea</i> . |
| t241 | Pla a 1.0101 | <i>Platanus acerifolia</i> . |
| t242 | Pla a 2 | <i>Platanus acerifolia</i> . |
| t243 | Pla a 3.0101 | <i>Platanus acerifolia</i> . |
| t244 | Cor a 1.0103 | <i>Corylus avellana</i> . |
| t245 | Aln g 1.0101 | <i>Alnus glutinosa</i> . |
| t246 | Cry j 1 | <i>Cryptomeria japonica</i> . |
| t280 | Locust tree | <i>Robinia pseudoacacia</i> . |
| t401 | Brazilian peppertree | <i>Schinus terebinthifolius</i> . |
| t402 | Mastic tree | <i>Pistacia lentiscus</i> . |
| t404 | Tree of heaven | <i>Ailanthus altissima</i> . |
| t406 | Date palm | <i>Phoenix dactylifera</i> . |
| a482 | Ole e 1 | <i>Olea europaea</i> (Olive Oil). |
| Mites | | |
| d207 | Blo t 5.0101 | <i>Blomia tropicalis</i> . |
| d208 | Lep d 2.0101 | <i>Lepidoglyphus destructor</i> . |
| Microorganisms, Molds, Yeast | | |
| m1 | <i>Penicillium chrysogenum</i> (<i>Penicillium notatum</i>) | <i>Penicillium chrysogenum</i> (<i>Penicillium notatum</i>). |
| m2 | <i>Cladosporium herbarum</i> (<i>Hormodendrum</i>) | <i>Cladosporium herbarum</i> (<i>Hormodendrum</i>). |
| m3 | <i>Aspergillus fumigatus</i> | <i>Aspergillus fumigatus</i> . |
| m4 | <i>Mucor racemosus</i> | <i>Mucor racemosus</i> . |
| m5 | <i>Candida albicans</i> | <i>Candida albicans</i> . |
| m7 | <i>Botrytis cinerea</i> | <i>Botrytis cinerea</i> . |
| m8 | <i>Drechslera halodes</i> (<i>Setomelanomma rostrata</i> , <i>Helminthosporium halodes</i> , <i>Helminthosporium</i> <i>interseminatum</i>). | <i>Drechslera halodes</i> (<i>Setomelanomma rostrata</i> , <i>Helminthosporium halodes</i>). |

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGIOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

| Allergen code | Allergen product | Source (taxonomical name) |
|---------------|------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| m9 | <i>Fusarium moniliforme</i> (<i>Fusarium proliferatum</i>) | <i>Fusarium moniliforme</i> (<i>Fusarium proliferatum</i>). |
| m10 | <i>Stemphylium botryosum</i> | <i>Stemphylium herbarum</i> (<i>Stemphylium botryosum</i>). |
| m11 | <i>Rhizopus nigricans</i> | <i>Rhizopus nigricans</i> . |
| m12 | <i>Aureobasidium pullulans</i> | <i>Aureobasidium pullulans</i> . |
| m13 | <i>Phoma betae</i> | <i>Phoma betae</i> . |
| m14 | <i>Epicoccum purpurascens</i> | <i>Epicoccum purpurascens</i> (<i>Epicoccum nigrum</i>). |
| m15 | <i>Trichoderma viride</i> | <i>Trichoderma viride</i> . |
| m16 | <i>Curvularia lunata</i> | <i>Curvularia lunata</i> , <i>Curvularia specifera</i> (K923044). |
| m17 | <i>Cladosporium fulvum</i> | <i>Cladosporium fulvum</i> . |
| m18 | <i>Fusarium culmorum</i> | <i>Fusarium culmorum</i> . |
| m19 | <i>Aspergillus versicolor</i> | <i>Aspergillus versicolor</i> . |
| m20 | <i>Mucor mucedo</i> | <i>Mucor mucedo</i> . |
| m21 | <i>Aspergillus clavatus</i> | <i>Aspergillus clavatus</i> . |
| m22 | <i>Micropolyspora faeni</i> | <i>Saccharopolyspora rectivirgula</i> (<i>Micropolyspora faeni</i>). |
| m23 | <i>Thermoactinomyces vulgaris</i> | <i>Thermoactinomyces vulgaris</i> . |
| m24 | <i>Stachybotrys atra</i> | <i>Stachybotrys chartarum</i> (<i>Stachybotrys atra</i>). |
| m24 | <i>Paecilomyces</i> spp | <i>Paecilomyces</i> spp. |
| m25 | <i>Aspergillus versicolor</i> | <i>Aspergillus versicolor</i> . |
| m25 | <i>Penicillium brevicompactum</i> | <i>Penicillium brevicompactum</i> . |
| m26 | <i>Cladosporium cladosporioides</i> | <i>Cladosporium cladosporioides</i> . |
| m26 | <i>Penicillium citrinum</i> | <i>Penicillium citrinum</i> . |
| m27 | <i>Penicillium</i> spp | <i>Penicillium</i> spp. |
| m29 | <i>Aspergillus repens</i> | <i>Aspergillus repens</i> . |
| m30 | <i>Penicillium roqueforti</i> | <i>Penicillium roqueforti</i> . |
| m32 | <i>Cladosporium cladosporioides</i> | <i>Cladosporium cladosporioides</i> . |
| m34 | <i>Serpula lacrymans</i> | <i>Serpula lacrymans</i> . |
| m36 | <i>Aspergillus terreus</i> | <i>Aspergillus terreus</i> . |
| m37 | <i>Trichophyton mentagrophytes</i> | <i>Trichophyton mentagrophytes</i> . |
| m40 | <i>Aspergillus amstelodami</i> | <i>Aspergillus amstelodami</i> . |
| m43 | <i>Saccharomyces Carlsberg</i> | <i>Saccharomyces carlsbergensis</i> . |
| m44 | <i>Saccharomyces cerevisiae</i> | <i>Saccharomyces cerevisiae</i> . |
| m45 | <i>Hormodendrum hordei</i> | <i>Hormodendrum hordei</i> . |
| m46 | <i>Bipolaris spicifera</i> | <i>Bipolaris spicifera</i> . |
| m47 | <i>Aspergillus nidulans</i> | <i>Aspergillus nidulans</i> . |
| m48 | <i>Aspergillus oryzae</i> | <i>Aspergillus oryzae</i> . |
| m49 | <i>Fusarium oxysporum</i> | <i>Fusarium oxysporum</i> . |
| m50 | <i>Micropolyspora faeni</i> | <i>Saccharopolyspora rectivirgula</i> (<i>Micropolyspora faeni</i>). |
| m51 | <i>Thermoactinomyces vulgaris</i> | <i>Thermoactinomyces vulgaris</i> . |
| m53 | <i>Microspora canis</i> | <i>Microsporum canis</i> (<i>Microspora canis</i>). |
| m54 | <i>Aspergillus flavus</i> | <i>Aspergillus flavus</i> . |
| m63 | <i>Helminthosporium intersemin</i> | <i>Helminthosporium intersemin</i> . |
| m66 | <i>Mucor plumbeus</i> | <i>Mucor plumbeus</i> . |
| m67 | <i>Mycogone</i> | <i>Mycogone perniciosa</i> . |
| m68 | <i>Nigrospora oryzae</i> | <i>Nigrospora oryzae</i> . |
| m69 | <i>Rhodotorula</i> | <i>Rhodotorula rubra</i> (<i>Rhodotorula mucilaginosa</i>). |
| m70 | <i>Malassezia furfur</i> (<i>Pityrosporum orbiculare</i>) | <i>Malassezia furfur</i> (<i>Pityrosporum orbiculare</i>). |
| m71 | <i>Spondylocladium</i> | <i>Spondylocladium</i> spp. |
| m72 | <i>Epidermophyton</i> | <i>Epidermophyton floccosum</i> . |
| m73 | <i>Epicoccum nigrum</i> | <i>Epicoccum purpurascens</i> (<i>Epicoccum nigrum</i>). |
| m80 | <i>Staphylococcal enterotoxin A</i> (<i>Sta a SEA</i>) | <i>Staphylococcus aureus</i> . |
| m80 | <i>Helminthosporium</i> spp | <i>Helminthosporium</i> spp. |
| m81 | <i>Staphylococcal enterotoxin B</i> (<i>Sta a SEB</i>) | <i>Staphylococcus aureus</i> . |
| m88 | <i>Stemphylium solani</i> | <i>Stemphylium solani</i> . |
| m93 | <i>Gliocladium fimbriatum</i> | <i>Gliocladium fimbriatum</i> . |
| m94 | <i>Phycomyces blakesleeanus</i> | <i>Phycomyces blakesleeanus</i> . |
| m201 | <i>Tilletia tritici</i> (<i>Ustilago nuda</i> , <i>Ustilago tritici</i>) (Barley smut) | <i>Tilletia tritici</i> (<i>Ustilago nuda</i> , <i>Ustilago tritici</i>). |
| m202 | <i>Acremonium kiliense</i> (<i>Cephalosporium acremonium</i>) | <i>Acremonium kiliense</i> (<i>Cephalosporium acremonium</i>). |
| m203 | <i>Trichosporon pullulans</i> | <i>Trichosporon pullulans</i> . |
| m204 | <i>Ulocladium chartarum</i> | <i>Ulocladium chartarum</i> . |
| m205 | <i>Trichophyton rubrum</i> | <i>Trichophyton rubrum</i> . |
| m207 | <i>Aspergillus niger</i> | <i>Aspergillus niger</i> . |
| m208 | <i>Chaetomium globosum</i> | <i>Chaetomium globosum</i> . |
| m209 | <i>Penicillium frequentans</i> | <i>Penicillium glabrum</i> (<i>Penicillium frequentans</i>). |
| m209 | <i>Stachybotrys chartarum</i> | <i>Stachybotrys chartarum</i> (<i>Stachybotrys atra</i>). |
| m210 | <i>Trichophyton mentagrophytes</i> var. <i>goetzii</i> | <i>Trichophyton mentagrophytes</i> var. <i>goetzii</i> . |
| m211 | <i>Trichophyton mentagrophytes</i> var. <i>interdigitale</i> | <i>Trichophyton mentagrophytes</i> var. <i>interdigitale</i> . |
| m211 | Oat smut | <i>Ustilago avenae</i> . |
| m212 | <i>Micropolyspora faeni</i> | <i>Saccharopolyspora rectivirgula</i> (<i>Micropolyspora faeni</i>). |
| m212 | <i>Geotrichum candidum</i> | <i>Geotrichum candidum</i> . |
| m213 | Bermuda grass smut | <i>Ustilago cynodontis</i> . |

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGIOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

| Allergen code | Allergen product | Source (taxonomical name) |
|-------------------------------|---------------------------------------------------------------|-------------------------------------------------------------------------|
| m214 | Johnson grass smut | <i>Sphacelotheca cruenta</i> . |
| m215 | Corn smut | <i>Ustilago maydis</i> . |
| m218 | Asp f 1.0101 | <i>Aspergillus fumigatus</i> . |
| a3050 | Asp r 1 | <i>Aspergillus restrictus</i> . |
| m219 | Asp f 2 | <i>Aspergillus fumigatus</i> . |
| m220 | Asp f 3.0101 | <i>Aspergillus fumigatus</i> . |
| m221 | Asp f 4 | <i>Aspergillus fumigatus</i> . |
| m222 | Asp f 6.0101 | <i>Aspergillus fumigatus</i> . |
| m223 | <i>Staphylococcal enterotoxin C (Sta a SEC)</i> | <i>Staphylococcus aureus</i> . |
| m224 | <i>Staphylococcal enterotoxin D (Sta a SED)</i> | <i>Staphylococcus aureus</i> . |
| m226 | <i>Staphylococcal enterotoxin TSST (Sta a TSST)</i> | <i>Staphylococcus aureus</i> . |
| m227 | <i>Malassezia</i> spp. (<i>Pityrosporum</i> spp.) | <i>Malassezia</i> spp. (<i>Pityrosporum</i> spp.). |
| m228 | <i>Aspergillus flavus</i> . | |
| m229 | Alt a 1.0101 | <i>Alternaria alternata (Alternaria tenuis)</i> . |
| m230 | Alt a 6.0101 | <i>Alternaria alternata (Alternaria tenuis)</i> . |
| m231 | Cla h 8.0101 | <i>Cladosporium herbarum (Hormodendrum)</i> . |
| m300 | <i>Eurotium</i> spp | <i>Eurotium</i> spp. |
| m304 | <i>Aspergillus oryzae</i> | <i>Aspergillus oryzae</i> . |
| m305 | <i>Penicillium brevicompactum</i> | <i>Penicillium brevicompactum</i> . |
| m309 | <i>Aspergillus terreus</i> | <i>Aspergillus terreus</i> . |
| m310 | <i>Aspergillus nidulans</i> | <i>Aspergillus nidulans</i> . |
| m311 | <i>Aspergillus flavus</i> | <i>Aspergillus flavus</i> . |
| m312 | <i>Aspergillus clavatus</i> | <i>Aspergillus clavatus</i> . |
| Epidermal & Animal | | |
| e6 | Guinea pig epithelium | <i>Cavia porcellus</i> . |
| e7 | Pigeon droppings | <i>Columba palumbus, Columba livia</i> . |
| e25 | Chicken serum | <i>Gallus domesticus (Gallus gallus domesticus; Gallus spp.)</i> . |
| e26 | Parrot serum | <i>Psittacoidea</i> spp. |
| e62 | Camel | <i>Camelus dromedaries</i> . |
| e70 | Goose feathers | <i>Anser anser</i> . |
| e71 | Mouse epithelium | <i>Mus musculus (Mus spp.)</i> . |
| e73 | Rat epithelium | <i>Rattus norvegicus</i> . |
| e74 | Rat urine proteins | <i>Rattus norvegicus, Rattus rattus</i> . |
| e75 | Rat serum proteins | <i>Rattus norvegicus, Rattus rattus</i> . |
| e76 | Mouse serum proteins | <i>Mus musculus (Mus spp.)</i> . |
| e77 | Budgerigar droppings | <i>Melopsittacus undulatus</i> . |
| e78 | Budgerigar feathers | <i>Melopsittacus undulatus</i> . |
| e79 | Budgerigar serum proteins | <i>Melopsittacus undulatus</i> . |
| e80 | Goat epithelium | <i>Capra hircus</i> . |
| e81 | Sheep epithelium | <i>Ovis aries (Ovis spp.)</i> . |
| e82 | Rabbit epithelium | <i>Oryctolagus cuniculus (Oryctolagus spp.)</i> . |
| e83 | Swine epithelium | <i>Sus scrofa (Sus scrofa domesticus; Sus spp.)</i> . |
| e84 | Hamster epithelium | <i>Cricetus cricetus, Mesocricetus auratus, and Phodopus sungorus</i> . |
| e85 | Chicken feathers | <i>Gallus domesticus (Gallus gallus domesticus; Gallus spp.)</i> . |
| e86 | Duck feathers | <i>Anas platyrhynchos</i> . |
| e87 | Rat epithelium, serum proteins, and urine proteins | <i>Rattus norvegicus Rattus rattus</i> . |
| e88 | Mouse epithelium, serum proteins, and urine proteins (mouse). | <i>Mus musculus (Mus spp.)</i> . |
| e89 | Turkey feathers | <i>Meleagris gallopavo</i> . |
| e90 | Budgerigar serum proteins, feathers, and droppings | <i>Melopsittacus undulatus</i> . |
| e91 | Pigeon serum proteins, feathers, and droppings | <i>Streptopelia roseogrisea, Psittacidae</i> spp. |
| e92 | Parrot serum proteins, feathers, and droppings | <i>Ara</i> spp. |
| e93 | Pigeon serum proteins | <i>Streptopelia roseogrisea</i> . |
| e94 | Fel d 1.0101 | <i>Felis domesticus</i> . |
| a345 | Fel d 1 | <i>Felis domesticus</i> . |
| e98 | Parrot droppings | <i>Psittacoidea</i> spp. |
| e101 | Can f 1.0101 | <i>Canis familiaris (Canis domesticus)</i> . |
| a174 | Can f 1 | <i>Canis familiaris (Canis domesticus)</i> . |
| e102 | Can f 2.0101 | <i>Canis familiaris (Canis domesticus)</i> . |
| e196 | Parakeet feathers | <i>Nymphicus hollandicus</i> . |
| e197 | Parakeet droppings | <i>Nymphicus hollandicus</i> . |
| e198 | Parakeet serum | <i>Nymphicus hollandicus</i> . |
| e199 | Canary bird serum | <i>Serinus canarius</i> . |
| e200 | Canary bird droppings | <i>Serinus canarius</i> . |
| e201 | Canary bird feathers (Canary feathers) | <i>Serinus canarius</i> . |
| e202 | Reindeer epithelium | <i>Rangifer tarandus</i> . |
| e203 | Mink epithelium | <i>Mustela</i> spp. |

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

| Allergen code | Allergen product | Source (taxonomical name) |
|---------------|---------------------------------|-----------------------------------------------------------------------------------|
| e204 | Bos d 6 | <i>Bos domesticus</i> (<i>Bos taurus</i> ; <i>Bos</i> spp.). |
| e205 | Horse, serum proteins | <i>Equus caballus</i> (<i>Equus</i> spp.). |
| e206 | Rabbit, serum proteins | <i>Oryctolagus cuniculus</i> (<i>Oryctolagus</i> spp.). |
| e208 | Chinchilla epithelium | <i>Chinchilla laniger</i> . |
| e209 | Gerbil epithelium | <i>Meriones unguiculatus</i> . |
| e210 | Fox epithelium | <i>Vulpes vulpes</i> . |
| e211 | Rabbit, urine proteins | <i>Oryctolagus cuniculus</i> (<i>Oryctolagus</i> spp.). |
| e212 | Swine, urine proteins | <i>Sus scrofa</i> (<i>Sus scrofa domesticus</i> ; <i>Sus</i> spp.). |
| e213 | Parrot feathers | <i>Ara</i> spp. |
| e214 | Finch feathers | <i>Lonchura domestica</i> . |
| e215 | Pigeon feathers | <i>Streptopelia roseogrisea</i> (<i>Streptopelia</i> spp.), <i>Columbia</i> spp. |
| e216 | Deer epithelium | <i>Dama dama</i> . |
| e217 | Ferret epithelium | <i>Mustela putorius</i> . |
| e218 | Chicken droppings | <i>Gallus domesticus</i> (<i>Gallus gallus domesticus</i> ; <i>Gallus</i> spp.). |
| e219 | Chicken, serum proteins | <i>Gallus domesticus</i> (<i>Gallus gallus domesticus</i> ; <i>Gallus</i> spp.). |
| e220 | Fel d 2, Cat serum albumin | <i>Felis domesticus</i> . |
| e221 | Can f 3 | <i>Canis familiaris</i> (<i>Canis domesticus</i>) (<i>Dog serum albumin</i>). |
| e222 | Swine serum albumin (Sus s PSA) | <i>Sus scrofa</i> (<i>Sus scrofa domesticus</i> ; <i>Sus</i> spp.). |
| e225 | Lovebird feathers | <i>Psittacoidea agapomis</i> . |
| e226 | Can f 5.0101 | <i>Canis familiaris</i> . |
| e227 | Equ c 1.0101 | <i>Equus caballus</i> . |
| e228 | Fel d 4.0101 | <i>Felis domesticus</i> . |
| e230 | Equ c 3 | <i>Equus caballus</i> . |
| e231 | Mus m 1 | <i>Mus musculus</i> . |
| Food | | |
| f9 | Rice | <i>Oryza sativa</i> . |
| f12 | Pea (green pea) | <i>Pisum sativum</i> . |
| f15 | White bean | <i>Phaseolus vulgaris</i> . |
| f19 | Cayenne pepper | <i>Capsicum frutescens</i> (<i>Capsicum annuum</i>). |
| f21 | Sugar cane | <i>Saccharum officinarum</i> . |
| f22 | Raspberry | <i>Rubus idaeus</i> . |
| f26 | Pork | <i>Sus scrofa</i> (<i>Sus scrofa domesticus</i> ; <i>Sus</i> spp.). |
| f29 | Watermelon | <i>Citrullus lanatus</i> (<i>Citrullus vulgaris</i>). |
| f31 | Carrot | <i>Daucus carota</i> . |
| f32 | Oyster mushroom | <i>Pleurotus ostreatus</i> . |
| f33 | Orange | <i>Citrus sinensis</i> . |
| f35 | Potato | <i>Solanum tuberosum</i> . |
| f43 | Mother's milk | <i>Homo sapiens</i> . |
| f44 | Strawberry | <i>Fragaria vesca</i> (<i>Fragaria</i> spp.). |
| f45 | Yeast, baker's | <i>Saccharomyces cerevisiae</i> . |
| f46 | Pepper, Red | <i>Capsicum annuum</i> . |
| f47 | Garlic | <i>Allium sativum</i> . |
| f48 | Onion | <i>Allium cepa</i> . |
| f49 | Apple | <i>Malus x domestica</i> (<i>Malus</i> spp.). |
| f51 | Bamboo shoot | <i>Phyllostachys pubescens</i> . |
| f52 | Cacao/chocolate | <i>Theobroma cacao</i> . |
| f54 | Sweet potato | <i>Ipomoea batatas</i> . |
| f55 | Common millet | <i>Panicum miliaceum</i> . |
| f56 | Foxtail millet | <i>Setaria italica</i> . |
| f57 | Japanese millet | <i>Echinochloa crus-galli</i> . |
| f58 | Pacific squid | <i>Todarodes pacificus</i> . |
| f59 | Octopus | <i>Octopus vulgaris</i> (<i>Octopus</i> spp.). |
| f63 | Kefir | NA. |
| f67 | Parmesan cheese | NA. |
| f81 | Cheese, cheddar type | NA. |
| f82 | Cheese, mold type | NA. |
| f83 | Chicken | <i>Gallus domesticus</i> (<i>Gallus gallus domesticus</i> ; <i>Gallus</i> spp.). |
| f86 | Parsley | <i>Petroselinum crispum</i> . |
| f87 | Melon | <i>Cucumis melo Cucumis melo + Citrullus lanatus</i> . |
| f88 | Mutton (lamb) | <i>Ovis aries</i> (<i>Ovis</i> spp.). |
| f90 | Malt | <i>Hordeum vulgare</i> . |
| f92 | Banana | <i>Musa</i> spp. |
| f93 | Cacao | <i>Theobroma cacao</i> . |
| f94 | Pear | <i>Pyrus communis</i> (<i>Pyrus</i> spp.). |
| f97 | Yam | <i>Dioscorea</i> spp. <i>Dioscorea opposita</i> . |
| f97 | Chamomile tea | <i>Matricaria chamomilla</i> . |
| f98 | Gladiin | <i>Triticum aestivum</i> (<i>Triticum</i> spp.). |
| f102 | Cantaloupe | <i>Cucumis melo var. cantalupensis</i> . |

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGIOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

| Allergen code | Allergen product | Source (taxonomical name) |
|---------------|-------------------------------------|-----------------------------------------------------------------------------------|
| f105 | Chocolate | <i>Theobroma cacao</i> . |
| f109 | Cottonseed | <i>Gossypium hirsutum</i> . |
| f110 | Giant radish | <i>Raphanus sativus</i> . |
| f118 | Zucchini | <i>Cucurbita pepo</i> . |
| f119 | Radish | <i>Raphanus sativus</i> . |
| f120 | Venison | <i>Capreolus capeolus</i> . |
| f121 | Pinto bean | <i>Phaseolus vulgaris</i> . |
| f122 | Cheese, American | NA. |
| f127 | Black-eyed pea | <i>Vigna unguiculata</i> . |
| f131 | Black Olive | <i>Olea europaea</i> . |
| f136 | Red beet | <i>Beta vulgaris var. conditiva</i> . |
| f139 | Goat's Cheese | <i>Capra aegagrus</i> . |
| f140 | Bran | NA. |
| f141 | Corn (vegetables) | <i>Zea mays</i> . |
| f152 | Green bell pepper | <i>Capsicum annuum</i> . |
| f155 | Brewer's yeast | <i>Saccharomyces carlsbergensis</i> . |
| f157 | Duck | <i>Anas domesticus</i> . |
| f158 | Goose | <i>Anser anser</i> . |
| f160 | Camembert cheese | NA. |
| f162 | Nectarine | <i>Prunus persica var. nucipersica</i> . |
| f163 | Kohlrabi | <i>Brassica oleracea var. gongylodes</i> . |
| f65 | Perch | |
| f166 | Leek | <i>Allium porrum</i> . |
| f170 | Cheese (Switzerland) (Swiss cheese) | NA. |
| f174 | Fig | <i>Ficus carica</i> . |
| f177 | Cranberry | <i>Vaccinium macrocarpon</i> . |
| f179 | Raisin | <i>Vitis</i> spp. |
| f182 | Lima bean | <i>Phaseolus lunatus</i> . |
| f198 | Flaxseed (bruised grain) | <i>Linum usitatissimum</i> . |
| f199 | Untreated native milk | <i>Bos domesticus</i> (<i>Bos taurus</i> ; <i>Bos</i> spp.). |
| f208 | Lemon | <i>Citrus limon</i> . |
| f209 | Grapefruit | <i>Citrus paradisi</i> . |
| f210 | Pineapple | <i>Ananas comosus</i> . |
| f211 | Blackberry | <i>Rubus fruticosus</i> . |
| f212 | Mushroom (champignon) | <i>Agaricus hortensis</i> (<i>Agaricus</i> spp.). |
| f213 | Rabbit | <i>Oryctolagus cuniculus</i> (<i>Oryctolagus</i> spp.). |
| f214 | Spinach | <i>Spinacia oleracea</i> . |
| f215 | Lettuce | <i>Lactuca sativa</i> . |
| f216 | Cabbage | <i>Brassica oleracea var. capitata</i> . |
| f217 | Brussels sprouts | <i>Brassica oleracea var. gem</i> . |
| f218 | Paprika, sweet pepper | <i>Capsicum annuum</i> . |
| f219 | Fennel seed | <i>Foeniculum vulgare</i> . |
| f219 | Sage | <i>Salvia officinalis</i> . |
| f220 | Cinnamon | <i>Cinnamomum</i> spp. |
| f221 | Coffee | <i>Coffea</i> spp. |
| f222 | Tea | <i>Camellia sinensis</i> . |
| f223 | Green olive | <i>Olea europaea</i> . |
| f225 | Summer squash, pumpkin | <i>Cucurbita pepo</i> . |
| f225 | Pumpkin | <i>Cucurbita maxima</i> . |
| f226 | Pumpkin seed | <i>Cucurbita pepo</i> . |
| f227 | Sugar-beet seed | <i>Beta vulgaris</i> . |
| f229 | Safflower Seed | <i>Carthamus tinctorius</i> . |
| f231 | Milk, boiled | <i>Bos domesticus</i> (<i>Bos taurus</i> ; <i>Bos</i> spp.). |
| f234 | Vanilla | <i>Vanilla planifolia</i> . |
| f237 | Apricot | <i>Prunus armeniaca</i> . |
| f241 | Gouda cheese | NA. |
| f242 | Cherry | <i>Prunus avium</i> . |
| f244 | Cucumber | <i>Cucumis sativus</i> . |
| f246 | Guar, guar gum | <i>Cyamopsis tetragonoloba</i> . |
| f247 | Honey | NA. |
| f248 | Rosemary | <i>Rosmarinus officinalis</i> . |
| f254 | Plaice | <i>Pleuronectes platessa</i> . |
| f255 | Plum | <i>Prunus domestica</i> , <i>Prunus americana</i> . |
| f258 | Squid | <i>Loligo</i> spp. |
| f259 | Grape | <i>Vitis vinifera</i> (<i>Vitis</i> spp.). |
| f260 | Broccoli | <i>Brassica oleracea var. italica</i> (<i>Brassica oleracea var. cultivar</i>). |
| f261 | Asparagus | <i>Asparagus officinalis</i> . |
| f262 | Aubergine, eggplant | <i>Solanum melongena</i> . |
| f263 | Green pepper | <i>Piper nigrum</i> , <i>Capsicum annuum</i> . |

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGIOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

| Allergen code | Allergen product | Source (taxonomical name) |
|---------------|--------------------------------------------|-------------------------------------------------------------|
| f264 | Eel | <i>Anguilla anguilla</i> . |
| f265 | Caraway | <i>Carum carvi</i> . |
| f265 | Cumin | <i>Cuminum cyminum</i> . |
| f266 | Mace | <i>Myristica fragrans</i> . |
| f267 | Cardamon | <i>Elettaria cardamomum</i> . |
| f268 | Clove | <i>Syzygium aromaticum</i> . |
| f269 | Basil | <i>Ocimum basilicum</i> . |
| f270 | Ginger | <i>Zingiber officinale</i> . |
| f271 | Anise | <i>Pimpinella anisum</i> . |
| f272 | Tarragon | <i>Artemisia dracunculus</i> . |
| f273 | Thyme | <i>Thymus vulgaris</i> . |
| f274 | Marjoram | <i>Origanum majorana</i> . |
| f275 | Lovage | <i>Levisticum officinale</i> . |
| f276 | Fennel, fresh | <i>Foeniculum vulgare</i> . |
| f277 | Dill | <i>Anethum graveolens</i> . |
| f278 | Bay leaf | <i>Laurus nobilis</i> . |
| f279 | Chili pepper | <i>Capsicum frutescens</i> . |
| f280 | Black pepper | <i>Piper nigrum</i> . |
| f281 | Curry (Santa Maria) | NA. |
| f282 | Nutmeg | <i>Myristica fragrans</i> . |
| f283 | Oregano | <i>Origanum vulgare</i> . |
| f284 | Turkey meat | <i>Meleagris gallopavo</i> . |
| f285 | Elk/moose meat | <i>Alces</i> spp. |
| f286 | Mare's milk | <i>Equus caballus</i> (<i>Equus</i> spp.). |
| f287 | Red kidney bean | <i>Phaseolus vulgaris</i> . |
| f288 | Blueberry | <i>Vaccinium myrtillus</i> (<i>Vaccinium</i> spp.). |
| f289 | Date | <i>Phoenix dactylifera</i> . |
| f291 | Cauliflower | <i>Brassica oleracea</i> var. <i>botrytis</i> . |
| f292 | Guava | <i>Psidium guajava</i> . |
| f293 | Papaya | <i>Carica papaya</i> . |
| f294 | Passion fruit, Maracuja | <i>Passiflora edulis</i> (<i>Passiflora</i> spp.). |
| f295 | Carambola | <i>Averrhoa carambola</i> . |
| f296 | Carob | <i>Ceratonia siliqua</i> . |
| f297 | Gum Arabic | <i>Acacia senegal</i> (<i>Acacia</i> spp.). |
| f298 | Tragacanth | <i>Astragalus</i> spp. |
| f299 | Sweet chestnut (chestnut) | <i>Castanea sativa</i> . |
| f300 | Pinto bean | <i>Phaseolus</i> spp. |
| f301 | Persimmon (kaki fruit, sharon) | <i>Diospyros kaki</i> . |
| f302 | Mandarin (tangerine, clementine, satsumas) | <i>Citrus reticulata</i> . |
| f305 | Fenugreek | <i>Trigonella foenum-graecum</i> . |
| f306 | Lime | <i>Citrus aurantifolia</i> . |
| f307 | Hake | <i>Merluccius merluccius</i> . |
| f308 | Sardine (pilchard) | <i>Sardina pilchardus</i> . |
| f310 | Blue vetch | <i>Lathyrus sativus</i> . |
| f311 | Megrin | <i>Lepidorhombus whiffiagonis</i> . |
| f315 | Green bean | <i>Phaseolus vulgaris</i> . |
| f316 | Rape seed | <i>Brassica napus</i> . |
| f317 | Coriander | <i>Coriandrum sativum</i> . |
| f318 | Jack fruit | <i>Artocarpus heterophyllus</i> . |
| f319 | Beetroot | <i>Beta vulgaris</i> . |
| f320 | Crayfish | <i>Astacus astacus</i> . |
| f321 | Horse meat | <i>Equus caballus</i> (<i>Equus</i> spp.). |
| f322 | Red currant | <i>Ribes sylvestre</i> . |
| f324 | Hop (fruit cone) | <i>Humulus lupulus</i> . |
| f325 | Saffron | <i>Colchicum autumnale</i> . |
| f328 | Fig | <i>Ficus carica</i> . |
| f329 | Watermelon | <i>Citrullus lanatus</i> . |
| f330 | Rose hip | <i>Rosa</i> spp. |
| f331 | Saffron | <i>Crocus sativus</i> . |
| f332 | Mint | <i>Mentha piperita</i> . |
| f333 | Linseed | <i>Linum usitatissimum</i> . |
| f336 | Jujube | <i>Ziziphus jujuba</i> . |
| f336 | Wine vinegar | <i>Vitis vinifera</i> (<i>Vitis</i> spp.). |
| f337 | Sole | <i>Solea solea</i> . |
| f337 | English sole | <i>Parophrys vetulus</i> . |
| f338 | Wine, white | <i>Vitis vinifera</i> (<i>Vitis</i> spp.). |
| f339 | Allspice | <i>Pimenta dioica</i> . |
| f339 | Wine, red | <i>Vitis vinifera</i> (<i>Vitis</i> spp.). |
| f341 | Cranberry | <i>Vaccinium oxycoccus</i> , <i>Vaccinium macrocarpon</i> . |
| f342 | Olive (black, fresh) | <i>Olea europaea</i> . |

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGIOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

| Allergen code | Allergen product | Source (taxonomical name) |
|-----------------------------|---------------------------------|--------------------------------------------------------------------------------|
| f343 | Raspberry | <i>Rubus idaeus</i> . |
| f344 | Sage | <i>Salvia officinalis</i> . |
| f346 | Chives | <i>Allium schoenoprasum</i> . |
| f347 | Quinoa | <i>Chenopodium quinoa</i> . |
| f348 | Litchi | <i>Litchi chinensis</i> . |
| f349 | Chum salmon roe | <i>Oncorhynchus keta</i> . |
| f358 | Artichoke | <i>Cynara scolymus</i> . |
| f360 | Yogurt | NA. |
| f368 | Black bass | <i>Micropterus dolomieu (Micropterus dolomieu)</i> . |
| f374 | Karaya gum | <i>Sterculia urens</i> . |
| f375 | Horseradish | <i>Armoracia rusticana</i> . |
| f377 | Maple syrup | NA. |
| f379 | Okra | <i>Abelmoschus esculentus</i> . |
| f382 | Beet, sugar | <i>Beta vulgaris var. altissima</i> . |
| f401 | Loquat | <i>Eriobotrya japonica</i> . |
| f402 | Fig | <i>Ficus carica</i> . |
| f403 | Brewer's yeast | <i>Saccharomyces cerevisiae</i> . |
| f405 | Mint | <i>Mentha</i> spp. |
| f406 | Arugula | <i>Eruca vesicaria</i> . |
| House Dust | | |
| h1 | Greer Labs., Inc | NA. |
| h2 | Hollister-Stier Labs | NA. |
| h6 | Japan | NA. |
| Venoms & Insects | | |
| i7 | Midge | <i>Chironomus yoshimatsui</i> . |
| i8 | Moth | <i>Bombyx mori</i> , <i>Heterocera</i> spp. |
| i47 | Water flea | <i>Daphnia</i> spp. |
| i49 | Deer fly | <i>Chrysops</i> spp. |
| i51 | Black ant | <i>Camponotus pennsylvanicus</i> . |
| i54 | Flea mix (dog/cat), common flea | <i>Ctenocephalides</i> spp. |
| i71 | Mosquito | <i>Aedes communis</i> , <i>Aedes</i> spp. and <i>Culex</i> spp. |
| i72 | Green nimitti | <i>Cladotanytarsus lewisi</i> . |
| i73 | Blood worm | <i>Chironomus thummi</i> , <i>Chironomusri parius</i> , <i>Chironomus</i> spp. |
| i75 | European hornet | <i>Vespa crabro</i> . |
| i76 | Berlin beetle | <i>Trogoderma angustum</i> . |
| i77 | European paper wasp | <i>Polistes dominulus</i> . |
| i78 | Fly | <i>Musca domestica</i> . |
| i80 | Bumblebee | <i>Bombus pennsylvanicus</i> . |
| i201 | Horse bot fly | <i>Gasterophilus intestinalis</i> . |
| i202 | Grain weevil | <i>Sitophilus granarius</i> . |
| i203 | Mediterranean flour moth | <i>Ephestia kuehniella (Anagasta kuehniella)</i> . |
| i204 | Horse fly | <i>Tabanus</i> spp. |
| i205 | Bumblebee | <i>Bombus terrestris</i> . |
| i208 | Api m 1.0101 | <i>Apis mellifera</i> . |
| a45 | Api m 1 | <i>Apis mellifera</i> . |
| i209 | Ves v 5.0101 | <i>Vespula vulgaris</i> . |
| a670 | Ves v 5 | <i>Vespula vulgaris</i> . |
| i210 | Pol d 5.0101 | <i>Polistes dominulus</i> . |
| i211 | Ves v 1.0101 | <i>Vespula vulgaris</i> . |
| i213 | Api m 4 | <i>Apis mellifera</i> . |
| i214 | Api m 2 | <i>Apis mellifera</i> . |
| i215 | Api m 3 | <i>Apis mellifera</i> . |
| i216 | Api m 5 | <i>Apis mellifera</i> . |
| i217 | Api m 10 | <i>Apis mellifera</i> . |
| i220 | Bla g 1.0101 | <i>Blattella germanica</i> . |
| i221 | Bla g 2.0101 | <i>Blattella germanica</i> . |
| i222 | Bla g 5.0101 | <i>Blattella germanica</i> . |
| i223 | Bla g 7 | <i>Blattella germanica</i> . |
| a46 | Api m 2 | <i>Apis mellifera</i> . |
| Miscellaneous | | |
| o1 | Cotton, crude fibers | <i>Gossypium</i> spp. |
| o3 | Cotton (treated) | <i>Gossypium</i> spp. |
| o70 | Seminal fluid | <i>Homo sapiens</i> . |
| o71 | <i>Staphylococcus aureus</i> | <i>Staphylococcus aureus</i> . |

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGIOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

| Allergen code | Allergen product | Source (taxonomical name) |
|---------------------|-------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| o72 | <i>Pichia pastoris</i> crude extract customer specific | <i>Pichia pastoris</i> . |
| o72 | Sperm-sediment | <i>Homo sapiens</i> . |
| o73 | <i>Pichia pastoris</i> crude extr. vector customer specific | <i>Pichia pastoris</i> . |
| o74 | <i>Pichia pastoris</i> with vector customer specific | <i>Pichia pastoris</i> . |
| o201 | Tobacco leaf, tobacco dust | <i>Nicotiana tabacum</i> . |
| o202 | <i>Artemia salina</i> , fish feed | <i>Artemia salina</i> . |
| o203 | Tetramin, fish feed | NA. |
| o207 | <i>Daphnia</i> , fish feed | <i>Daphnia</i> spp. |
| o211 | Mealworm | <i>Tenebrio molitor</i> . |
| o212 | Streptavidin | <i>Streptomyces avidini</i> . |
| o213 | MBP (maltose binding protein) | <i>Escherichia coli</i> . |
| o214 | CCD; MUXF3 from bromelain | <i>Ananas comosus</i> . |
| o72 | Enterotoxin A (Sta a SEA) | <i>Staphylococcus aureus</i> . |
| o73 | Enterotoxin B (Sta a SEB) | <i>Staphylococcus aureus</i> . |
| Parasites | | |
| p1 | <i>Ascaris</i> | <i>Ascaris suum</i> . |
| p2 | <i>Echinococcus</i> | <i>Echinococcus granulosus</i> . |
| p3 | <i>Schistosoma</i> | <i>Schistosoma mansoni</i> . |
| p4 | <i>Anisakis</i> (Herring Worm) | <i>Anisakis simplex</i> (<i>Anisakis</i> spp.). |
| p5 | <i>Toxocara canis</i> | <i>Toxocara canis</i> . |
| p10 | Ani s 3.0101 | <i>Anisakis simplex</i> (<i>Anisakis</i> spp.). |
| p11 | Ani s 1 | <i>Anisakis simplex</i> (<i>Anisakis</i> spp.). |
| Occupational | | |
| k4 | Threshing dust | NA. |
| k5 | Flax | NA. |
| k7 | Hay Dust | NA. |
| k8 | Hop (hops) | <i>Humulus lupulus</i> . |
| k12 | Grain mill dust | NA. |
| k14 | Kapok | NA. |
| k20 | Sheep's wool (treated) (wool) | <i>Ovis aries</i> (<i>Ovis</i> spp.). |
| k21 | Sheep's wool (Untreated) | <i>Ovis aries</i> (<i>Ovis</i> spp.). |
| k23 | Straw Dust | NA. |
| k33 | Oak | NA. |
| k70 | Green coffee bean | <i>Coffea</i> spp. |
| k71 | Castor bean | <i>Ricinus communis</i> . |
| k72 | Ispaghula | <i>Plantago psyllium/Plantago ovata</i> . |
| k73 | Silk waste | NA. |
| k74 | Silk | <i>Bombyx mori</i> . |
| k75 | Isocyanate TDI (Toluene diisocyanate) | NA. |
| k76 | Isocyanate MDI (Diphenylmethane diisocyanate) | NA. |
| k77 | Isocyanate HDI (Hexamethylen diisocyanate) | NA. |
| k78 | Ethylene oxide | NA. |
| k79 | Phthalic anhydride | NA. |
| k80 | Formaldehyde/Formalin | NA. |
| k81 | <i>Ficus</i> | <i>Ficus benjamina</i> (<i>Ficus</i> spp.). |
| k83 | Cotton seed | <i>Gossypium hirsutum</i> . |
| k84 | Sunflower seed | <i>Helianthus annuus</i> . |
| k85 | Chloramin T | NA. |
| k86 | Trimellitic anhydride, TMA | NA. |
| k87 | Asp o 21, alpha-amylase | <i>Aspergillus oryzae</i> . |
| k89 | Orris root | <i>Iris florentina</i> . |
| k99 | HSA (Human Serum Albumin) (Hom s HSA) | <i>Homo sapiens</i> . |
| k201 | Car p 1, Papain | <i>Carica papaya</i> . |
| k202 | Ana c 2, Bromelain | <i>Ananas comosus</i> . |
| k204 | Maxatase | <i>Bacillus licheniformis</i> . |
| k205 | Alcalase | <i>Bacillus</i> spp. |
| k206 | Savinase, Protease 1 (Bac I Subtilisin) | <i>Bacillus</i> spp. |
| k208 | Gal d 4, Lysozyme | <i>Gallus domesticus</i> (<i>Gallus gallus domesticus</i> ; <i>Gallus</i> spp.). |
| k209 | Hexahydrophthalic anhydrid | NA. |
| k210 | Maleic anhydride | NA. |
| k211 | Methyltetrahydrophthalic anhydrid | NA. |
| k212 | Abachi wood dust | <i>Triplachiton scleroxylon</i> . |
| k213 | Pepsin (Sus s Pepsin) | <i>Sus scrofa</i> (<i>Sus scrofa domesticus</i> ; <i>Sus</i> spp.). |
| k213 | TCPA | NA. |
| k214 | Bougainvillea | <i>Bougainvillea</i> spp. |
| k225 | Horse radish peroxidase (Arm r HRP) | <i>Armoracia rusticana</i> . |

TABLE 1—CLASS II EXEMPT ALLERGENS UNDER § 866.5750—RADIOALLERGIOSORBENT (RAST) IMMUNOLOGICAL TEST SYSTEMS—Continued

| Allergen code | Allergen product | Source (taxonomical name) |
|---------------|---------------------------------------------------|------------------------------------|
| k226 | Ascorbate oxidase (Cuc p ascorbate oxidase) | <i>Cucurbita pepo.</i> |
| k301 | Flour dust | <i>Triticum</i> spp. |
| k501 | Savinase customer specific | Proprietary knowledge of customer. |
| k502 | Lipolase customer specific | Proprietary knowledge of customer. |
| k503 | Termamyl customer specific | Proprietary knowledge of customer. |
| k504 | Clazinase customer specific | Proprietary knowledge of customer. |

■ 66. In § 866.5910, revise paragraph (b) to read as follows:

§ 866.5910 Quality control material for cystic fibrosis nucleic acid assays.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays.” See § 866.1(e) for the availability of this guidance document.

PART 868—ANESTHESIOLOGY DEVICES

■ 67. The authority citation for part 868 continues to read as follows:

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

■ 68. In § 868.1040, revise paragraph (b) to read as follows:

§ 868.1040 Powered algometer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

■ 69. In § 868.2385, revise paragraph (b) to read as follows:

§ 868.2385 Nitrogen dioxide analyzer.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a standalone nitrogen dioxide analyzer and not those that are components of nitric oxide delivery systems intended to monitor nitrogen dioxide levels during inhaled nitric oxide therapy, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The special control is FDA’s “Guidance Document for Premarket Notification Submissions for Nitric Oxide Administration Apparatus, Nitric Oxide Analyzer, and Nitrogen Dioxide

Analyzer.” See § 868.1(e) for the availability of this guidance document.

■ 70. In § 868.2500, revise paragraph (b) to read as follows:

§ 868.2500 Cutaneous oxygen (PcO2) monitor.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The special control is FDA’s “Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO2) and Oxygen (PcO2) Monitors; Guidance for Industry and FDA.” See § 868.1(e) for the availability of this guidance document.

■ 71. In § 868.2550, revise paragraph (b) to read as follows:

§ 868.2550 Pneumotachometer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

■ 72. In § 868.5180, revise paragraph (b) to read as follows:

§ 868.5180 Rocking bed.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

■ 73. In § 868.6250, revise paragraph (b) to read as follows:

§ 868.6250 Portable air compressor.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9.

PART 870—CARDIOVASCULAR DEVICES

■ 74. The authority citation for part 870 continues to read as follows:

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

■ 75. In § 870.1330, revise paragraph (b) to read as follows:

§ 870.1330 Catheter guide wire.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a torque device that is manually operated, non-patient contacting, and intended to manipulate non-cerebral vascular guide wires, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 76. In § 870.1390, revise paragraph (b) to read as follows:

§ 870.1390 Trocar.

* * * * *

(b) *Classification.* Class II (special controls). Except for trocars that are reprocessed for multiple use, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 77. In § 870.1650, revise paragraph (b) to read as follows:

§ 870.1650 Angiographic injector and syringe.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a non-patient contacting balloon inflation syringe intended only to inflate/deflate balloon catheters and monitor pressure within the balloon, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 78. In § 870.1875, revise paragraph (b)(2) to read as follows:

§ 870.1875 Stethoscope.

* * * * *

(b) * * *

(2) *Classification.* Class II (special controls). The device, when it is a lung sound monitor, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 79. In § 870.2675, revise paragraph (b) to read as follows:

§ 870.2675 Oscillometer.

* * * * *

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 80. In § 870.2770, revise paragraph (b) to read as follows:

§ 870.2770 Impedance plethysmograph.

* * * * *

(b) Classification. Class II (special controls). The device, when it is a body composition analyzer which is not intended to diagnose or treat any medical condition, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 81. In § 870.4280, revise paragraph (b) to read as follows:

§ 870.4280 Cardiopulmonary prebypass filter.

* * * * *

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 82. In § 870.4290, revise paragraph (b) to read as follows:

§ 870.4290 Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting.

* * * * *

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 83. In § 870.4340, revise paragraph (b) to read as follows:

§ 870.4340 Cardiopulmonary bypass level sensing monitor and/or control.

* * * * *

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 84. In § 870.4400, revise paragraph (b) to read as follows:

§ 870.4400 Cardiopulmonary bypass blood reservoir.

* * * * *

(b) Classification. Class II (special controls), except that a reservoir that contains a defoamer or filter is classified into the same class as the defoamer or filter. The device, when it is a cardiopulmonary bypass blood reservoir that does not contain defoamers or

blood filters, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 85. In § 870.4420, revise paragraph (b) to read as follows:

§ 870.4420 Cardiopulmonary bypass cardiotomy return sucker.

* * * * *

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

■ 86. In § 870.4430, revise paragraph (b) to read as follows:

§ 870.4430 Cardiopulmonary bypass intracardiac suction control.

* * * * *

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9.

PART 872—DENTAL DEVICES

■ 87. The authority citation for part 872 continues to read as follows:

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

■ 88. In § 872.1720, revise paragraph (b) to read as follows:

§ 872.1720 Pulp tester.

* * * * *

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

■ 89. In § 872.3260, revise paragraph (b) to read as follows:

§ 872.3260 Cavity varnish.

* * * * *

(b) Classification. Class II (special controls). The device, when it is an external cleaning solution, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

■ 90. In § 872.3300, revise paragraph (b) to read as follows:

§ 872.3300 Hydrophilic resin coating for dentures.

* * * * *

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

■ 91. In § 872.3540, revise paragraph (b)(2) introductory text to read as follows:

§ 872.3540 OTC denture cushion or pad.

* * * * *

(b) * * * (2) Class II (special controls) if the OTC denture cushion or pad is made of a material other than wax-impregnated cotton cloth or if the intended use of the device differs from that described in paragraph (b)(1) of this section. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. The special controls for this device are FDA's:

* * * * *

■ 92. In § 872.3560, revise paragraph (b) introductory text to read as follows:

§ 872.3560 OTC denture reliner.

* * * * *

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. The special controls for this device are FDA's:

* * * * *

■ 93. In § 872.3590, revise paragraph (b) to read as follows:

§ 872.3590 Preformed plastic denture tooth.

* * * * *

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

■ 94. In § 872.3600, revise paragraph (b) introductory text to read as follows:

§ 872.3600 Partially fabricated denture kit.

* * * * *

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. The special controls for this device are FDA's:

* * * * *

■ 95. In § 872.3890, revise paragraph (b) to read as follows:

§ 872.3890 Endodontic stabilizing splint.

* * * * *

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

■ 96. In § 872.5550, revise paragraph (b)(2) to read as follows:

§ 872.5550 Teething ring.

* * * * *

(b) * * *

(2) Class II (special controls) if the teething ring contains a fluid, such as water. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

■ 97. In § 872.6770, revise paragraph (b) to read as follows:

§ 872.6770 Cartridge syringe.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9.

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 98. The authority citation for part 874 continues to read as follows:

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

■ 99. In § 874.1090, revise paragraph (b) to read as follows:

§ 874.1090 Auditory impedance tester.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a tympanometer or auditory impedance tester that complies with FDA-recognized consensus standard ANSI S3.39, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 100. In § 874.1120, revise paragraph (b) to read as follows:

§ 874.1120 Electronic noise generator for audiometric testing.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 101. In § 874.1325, revise paragraph (b) to read as follows:

§ 874.1325 Electroglottograph.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 102. In § 874.3310, revise paragraph (b) to read as follows:

§ 874.3310 Hearing aid calibrator and analysis system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in

subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 103. In § 874.3320, revise paragraph (b) to read as follows:

§ 874.3320 Group hearing aid or group auditory trainer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 104. In § 874.3330, revise paragraph (b) to read as follows:

§ 874.3330 Master hearing aid.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 105. In § 874.3430, revise paragraph (b) to read as follows:

§ 874.3430 Middle ear mold.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

■ 106. In § 874.3730, revise paragraph (b) to read as follows:

§ 874.3730 Laryngeal prosthesis (Taub design).

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a voice amplification device, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

■ 107. The authority citation for part 876 continues to read as follows:

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

■ 108. In § 876.1500, revise paragraph (b)(1) to read as follows:

§ 876.1500 Endoscope and accessories.

* * * * *

(b) * * *
 (1) Class II (special controls). The device, when it is an endoscope disinfectant basin, which consists solely of a container that holds disinfectant and endoscopes and accessories; an endoscopic magnetic retriever intended for single use; sterile scissors for cystoscope intended for single use; a disposable, non-powered endoscopic grasping/cutting instrument intended

for single use; a diagnostic incandescent light source; a fiberoptic photographic light source; a routine fiberoptic light source; an endoscopic sponge carrier; a xenon arc endoscope light source; an endoscope transformer; an LED light source; or a gastroenterology-urology endoscopic guidewire, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

* * * * *

■ 109. In § 876.4020, revise paragraph (b) to read as follows:

§ 876.4020 Fiberoptic light ureteral catheter.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 110. In § 876.4270, revise paragraph (b) to read as follows:

§ 876.4270 Colostomy rod.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 111. In § 876.4400, revise paragraph (b) to read as follows:

§ 876.4400 Hemorrhoidal ligator.

* * * * *

(b) *Classification.* Class II (special controls). Except for a hemostatic metal clip intended for use in the gastrointestinal tract, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 112. In § 876.4500, revise paragraph (b) to read as follows:

§ 876.4500 Mechanical lithotripter.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a biliary mechanical lithotripter, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 113. In § 876.4770, revise paragraph (b) to read as follows:

§ 876.4770 Urethrotome.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 114. In § 876.5010, revise paragraph (b) to read as follows:

§ 876.5010 Biliary catheter and accessories.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a bile collecting bag or a surgical biliary catheter that does not include a balloon component, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 115. In § 876.5025, revise paragraph (b) introductory text to read as follows:

§ 876.5025 Vibrator for climax control of premature ejaculation.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. The special controls for this device are:

* * * * *

■ 116. In § 876.5160, revise the section heading and paragraph (b) to read as follows:

§ 876.5160 Urological clamp.

* * * * *

(b) *Classification.* Class I (general controls). Except when intended for internal use, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 117. In § 876.5365, revise paragraph (b) to read as follows:

§ 876.5365 Esophageal dilator.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 118. In § 876.5520, revise paragraph (b)(1) to read as follows:

§ 876.5520 Urethral dilator.

* * * * *

(b) * * *

(1) Class II (special controls). Except when it is a mechanical urethral dilator, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

* * * * *

■ 119. In § 876.5630, revise paragraph (b) to read as follows:

§ 876.5630 Peritoneal dialysis system and accessories.

* * * * *

(b) *Classification.* Class II (special controls). The following accessories are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9: A catheter finger grip that is non-patient contacting and intended for single use with a peritoneal catheter; a continuous ambulatory peritoneal dialysis (CAPD) belt; and a catheter stand that does not include weigh scales.

■ 120. In § 876.5665, revise paragraph (b) to read as follows:

§ 876.5665 Water purification system for hemodialysis.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a water purification subsystem disinfectant, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 121. In § 876.5895, revise paragraph (b) to read as follows:

§ 876.5895 Ostomy irrigator.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

■ 122. In § 876.5980, revise paragraph (b)(1) to read as follows:

§ 876.5980 Gastrointestinal tube and accessories.

* * * * *

(b) * * *

(1) Class II (special controls). The barium enema retention catheter and tip with or without a bag that is a gastrointestinal tube and accessory or a gastronomy tube holder accessory is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

* * * * *

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 123. The authority citation for part 878 continues to read as follows:

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

■ 124. In § 878.4370, revise paragraph (b) to read as follows:

§ 878.4370 Surgical drape and drape accessories.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an ear, nose, and throat surgical drape, a latex

sheet drape with self-retaining finger cot, a disposable urological drape, a Kelly pad, an ophthalmic patient drape, an ophthalmic microscope drape, an internal drape retention ring (wound protector), or a surgical drape that does not include an antimicrobial agent, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9.

■ 125. In § 878.4495, revise paragraph (b) to read as follows:

§ 878.4495 Stainless steel suture.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a steel monofilament suture that is uncoated and does not incorporate barbs, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9. The special control for this device is FDA's "Class II Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA." See § 878.1(e) for the availability of this guidance document.

■ 126. In § 878.4580, revise paragraph (b) to read as follows:

§ 878.4580 Surgical lamp.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an operating room lamp, a surgical instrument light, a surgical floor standing light, an endoscopic surgical light, a surgical light connector, a ceiling mounted surgical light, a surgical light carrier, surgical light accessories, a surgical lamp, a remote illuminator, or an incandescent surgical lamp, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9.

■ 127. In § 878.5070, revise paragraph (b) to read as follows:

§ 878.5070 Air-handling apparatus for a surgical operating room.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an air handling bench apparatus, an air handling room apparatus, or an air handling enclosure apparatus, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 128. The authority citation for part 880 continues to read as follows:

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

- 129. In § 880.5580, revise paragraph (b) introductory text to read as follows:

§ 880.5580 Acupuncture needle.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an acupuncture point locator or a single use acupuncture needle, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9. Acupuncture needles must comply with the following special controls:

- * * * * *
- 130. In § 880.5680, revise paragraph (b) to read as follows:

§ 880.5680 Pediatric position holder.

* * * * *

(b) *Classification.* Class I (general controls). Except when the device is an infant positioner for prescription use in highly monitored settings or an infant sleep position holder, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9. The device is exempt from the good manufacturing practice regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

- 131. In § 880.5780, revise paragraph (a)(2) to read as follows:

§ 880.5780 Medical support stocking.

(a) * * *

(2) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

- * * * * *
- 132. In § 880.6250, revise paragraph (b) to read as follows:

§ 880.6250 Non-powdered patient examination glove.

* * * * *

(b) *Classification.* Class I (general controls). The device, when it is a finger cot, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

- 133. In § 880.6375, revise paragraph (b) to read as follows:

§ 880.6375 Patient lubricant.

* * * * *

(b) *Classification.* Class I (general controls). Except when the device is a vaginal patient lubricant or an oral

lubricant, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

- 134. In § 880.6760, revise paragraph (b) to read as follows:

§ 880.6760 Protective restraint.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9.

PART 882—NEUROLOGICAL DEVICES

- 135. The authority citation for part 882 continues to read as follows:

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

- 136. In § 882.1020, revise paragraph (b) to read as follows:

§ 882.1020 Rigidity analyzer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

- 137. In § 882.1030, revise paragraph (b) to read as follows:

§ 882.1030 Ataxiagraph.

* * * * *

(b) *Classification.* Class I (general controls). Except when the device is intended to provide an interpretation or a clinical implication of the measurement, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

- 138. In § 882.1470, revise paragraph (b) introductory text to read as follows:

§ 882.1470 Computerized cognitive assessment aid.

* * * * *

(b) *Classification.* Class II (special controls). Except when the computerized cognitive assessment aid is intended for diagnostic assessment of specific diseases or conditions and relies on inputs from visual cues, auditory cues, and/or functional use of the hand, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. The special control(s) for this device are:

- * * * * *
- 139. In § 882.1540, revise paragraph (b) to read as follows:

§ 882.1540 Galvanic skin response measurement device.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

- 140. In § 882.1560, revise paragraph (b) to read as follows:

§ 882.1560 Skin potential measurement device.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

- 141. In § 882.1855, revise paragraph (b) to read as follows:

§ 882.1855 Electroencephalogram (EEG) telemetry system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

- 142. In § 882.4060, revise paragraph (b) to read as follows:

§ 882.4060 Ventricular cannula.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

- 143. In § 882.4545, revise paragraph (b) to read as follows:

§ 882.4545 Shunt system implantation instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9.

- 144. In § 882.5895, revise paragraph (b) introductory text to read as follows:

§ 882.5895 Vibratory counter-stimulation device.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. The special controls for this device are:

* * * * *

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

- 145. The authority citation for part 884 continues to read as follows:

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

■ 146. In § 884.1630, revise paragraph (b) to read as follows:

§ 884.1630 Colposcope.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a standard colposcope (or colpomicroscope) that uses only a white light source, does not use filters other than a green filter, does not include image analysis software, and is not smartphone-based, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 147. In § 884.2990, revise paragraph (b) to read as follows:

§ 884.2990 Breast lesion documentation system.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a breast examination recording sheet, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9. The special control is FDA's guidance entitled "Class II Special Controls Guidance Document: Breast Lesion Documentation System." See § 884.1(e) for the availability of this guidance document.

■ 148. In § 884.3200, revise paragraph (b) to read as follows:

§ 884.3200 Cervical drain.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 149. In § 884.4400, revise paragraph (b) to read as follows:

§ 884.4400 Obstetric forceps.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 150. In § 884.4530, revise paragraph (b)(1) to read as follows:

§ 884.4530 Obstetric-gynecologic specialized manual instrument.

* * * * *

(b) * * *

(1) Class II (special controls). The device, when it is an umbilical clamp with or without a cutter, a uterine tenaculum which is sterile and does not use suction and is intended for single use, a nonmetal vaginal speculum, or a fiberoptic nonmetal vaginal speculum, is exempt from the premarket

notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

* * * * *

■ 151. In § 884.4900, revise paragraph (b) to read as follows:

§ 884.4900 Obstetric table and accessories.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 152. In § 884.5200, revise paragraph (b) introductory text to read as follows:

§ 884.5200 Hemorrhoid prevention pressure wedge.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9. The special controls for this device are:

* * * * *

■ 153. In § 884.5390, revise paragraph (b) to read as follows:

§ 884.5390 Perineal heater.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 154. In § 884.5400, revise paragraph (b) to read as follows:

§ 884.5400 Menstrual cup.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 155. In § 884.5425, revise paragraph (b)(2) to read as follows:

§ 884.5425 Scented or scented deodorized menstrual pad.

* * * * *

(b) * * *

(2) Class II (special controls) for scented or scented deodorized menstrual pads made of materials not described in paragraph (b)(1). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 156. In § 884.5435, revise paragraph (b) to read as follows:

§ 884.5435 Unscented menstrual pad.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9 only when the device is made of common cellulosic and synthetic material with an established safety profile.

■ 157. In § 884.6120, revise paragraph (b) to read as follows:

§ 884.6120 Assisted reproduction accessories.

* * * * *

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing). The device, when it is a simple embryo incubator with only temperature, gas, and humidity control; a syringe pump; a collection tube warmer; a dish/plate/microscope stage warmer; or a controlled-rate cryopreservation freezer, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 158. In § 884.6130, revise paragraph (b) to read as follows:

§ 884.6130 Assisted reproduction microtools.

* * * * *

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing). The device, when the assisted reproduction microtools (pipettes) are manufactured from glass, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 159. In § 884.6150, revise paragraph (b) to read as follows:

§ 884.6150 Assisted reproduction micromanipulators and microinjectors.

* * * * *

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

■ 160. In § 884.6160, revise paragraph (b) to read as follows:

§ 884.6160 Assisted reproduction labware.

* * * * *

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing). The device, when

it is a dish or plate intended for general assisted reproduction technology procedures, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

PART 886—OPHTHALMIC DEVICES

■ 161. The authority citation for part 886 continues to read as follows:
Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 162. In § 886.1120, revise paragraph (b) to read as follows:

§ 886.1120 Ophthalmic camera.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is a photorefractor or a general-use ophthalmic camera, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 163. In § 886.1250, revise paragraph (b) to read as follows:

§ 886.1250 Euthyscope.

* * * * *

(b) *Classification.* (1) Class I (general controls) for the battery-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

(2) Class II (special controls) for the AC-powered device. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 164. In § 886.1570, revise paragraph (b) to read as follows:

§ 886.1570 Ophthalmoscope.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an AC-powered ophthalmoscope, a battery-powered ophthalmoscope, or a hand-held ophthalmoscope replacement battery, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 165. In § 886.1780, revise paragraph (b)(1) to read as follows:

§ 886.1780 Retinoscope.

* * * * *

(b) * * *

(1) Class II (special controls) for the AC-powered device. The device is exempt from the premarket notification procedures in subpart E of part 807 of

this chapter subject to the limitations in § 886.9.

* * * * *

■ 166. In § 886.1850, revise paragraph (b) to read as follows:

§ 886.1850 AC-powered slitlamp biomicroscope.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is intended only for the visual examination of the anterior segment of the eye, is classified as Group 1 per FDA-recognized consensus standard ANSI Z80.36, does not provide any quantitative output, and is not intended for screening or automated diagnostic indications, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 167. In § 886.1945, revise paragraph (b) to read as follows:

§ 886.1945 Transilluminator.

* * * * *

(b) *Classification.* (1) Class I (general controls) for the battery-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

(2) Class II (special controls) for the AC-powered device. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 168. In § 886.3320, revise paragraph (b) to read as follows:

§ 886.3320 Eye sphere implant.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is an ocular peg which is supplied sterile only, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 169. In § 886.4070, revise paragraph (b) to read as follows:

§ 886.4070 Powered corneal burr.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 170. In § 886.4150, revise paragraph (b) to read as follows:

§ 886.4150 Vitreous aspiration and cutting instrument.

* * * * *

(b) *Classification.* Class II (special controls). The device, when it is phacofragmentation unit replacement tubing, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 171. In § 886.4250, revise paragraph (b) to read as follows:

§ 886.4250 Ophthalmic electrolysis unit.

* * * * *

(b) *Classification.* (1) Class I (general controls) for the battery-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

(2) Class II (special controls) for the AC-powered device. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 172. In § 886.4335, revise paragraph (b) to read as follows:

§ 886.4335 Operating headlamp.

* * * * *

(b) *Classification.* (1) Class I (general controls) for the battery-powered device. The battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

(2) Class II (special controls) for the AC-powered device. The AC-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 173. In § 886.4400, revise paragraph (b) to read as follows:

§ 886.4400 Electronic metal locator.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 174. In § 886.4440, revise paragraph (b) to read as follows:

§ 886.4440 AC-powered magnet.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

■ 175. In § 886.4790, revise paragraph (b) to read as follows:

§ 886.4790 Ophthalmic sponge.

* * * * *

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 886.9.

PART 888—ORTHOPEDIC DEVICES

■ 176. The authority citation for part 888 continues to read as follows:

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

■ 177. In § 888.1240, revise paragraph (b) to read as follows:

§ 888.1240 AC-powered dynamometer.
* * * * *

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 888.9.

■ 178. In § 888.4580, revise paragraph (b) to read as follows:

§ 888.4580 Sonic surgical instrument and accessories/attachments.
* * * * *

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 888.9.

PART 890—PHYSICAL MEDICINE DEVICES

■ 179. The authority citation for part 890 continues to read as follows:

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

■ 180. In § 890.1450, revise paragraph (b) to read as follows:

§ 890.1450 Powered reflex hammer.
* * * * *

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

■ 181. In § 890.5100, revise paragraph (b) to read as follows:

§ 890.5100 Immersion hydrobath.
* * * * *

(b) *Classification*. Class II (special controls). The device, when it is a hydromassage bath or a powered sitz bath, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

■ 182. In § 890.5110, revise paragraph (b) to read as follows:

§ 890.5110 Paraffin bath.
* * * * *

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

■ 183. In § 890.5250, revise paragraph (b) to read as follows:

§ 890.5250 Moist steam cabinet.
* * * * *

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

■ 184. In § 890.5360, revise paragraph (b) to read as follows:

§ 890.5360 Measuring exercise equipment.
* * * * *

(b) *Classification*. Class II (special controls). The device, when it is a measuring exerciser, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

■ 185. In § 890.5500, revise paragraph (b) to read as follows:

§ 890.5500 Infrared lamp.
* * * * *

(b) *Classification*. Class II (special controls). The device, when it is an infrared therapeutic heating lamp, is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

■ 186. In § 890.5575, revise paragraph (b) to read as follows:

§ 890.5575 Powered external limb overload warning device.
* * * * *

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 890.9.

PART 892—RADIOLOGY DEVICES

■ 187. The authority citation for part 892 continues to read as follows:

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

■ 188. In § 892.1000, revise paragraph (b) to read as follows:

§ 892.1000 Magnetic resonance diagnostic device.
* * * * *

(b) *Classification*. Class II (special controls). A magnetic resonance imaging disposable kit intended for use with a magnetic resonance diagnostic device only is exempt from the premarket notification procedures in subpart E of

part 807 of this chapter subject to the limitations in § 892.9.

■ 189. In § 892.1560, revise paragraph (b) to read as follows:

§ 892.1560 Ultrasonic pulsed echo imaging system.
* * * * *

(b) *Classification*. Class II (special controls). A biopsy needle guide kit intended for use with an ultrasonic pulsed echo imaging system only is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 190. In § 892.1610, revise paragraph (b) to read as follows:

§ 892.1610 Diagnostic x-ray beam-limiting device.
* * * * *

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 191. In § 892.1650, revise paragraph (b) to read as follows:

§ 892.1650 Image-intensified fluoroscopic x-ray system.
* * * * *

(b) *Classification*. Class II (special controls). An anthrogram tray or radiology dental tray intended for use with an image-intensified fluoroscopic x-ray system only is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9. In addition, when intended as an accessory to the device described in paragraph (a) of this section, the fluoroscopic compression device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 192. In § 892.1670, revise paragraph (b) to read as follows:

§ 892.1670 Spot-film device.
* * * * *

(b) *Classification*. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 193. In § 892.1680, revise paragraph (b) to read as follows:

§ 892.1680 Stationary x-ray system.
* * * * *

(b) *Classification*. Class II (special controls). A radiographic contrast tray or radiology diagnostic kit intended for use with a stationary x-ray system only is exempt from the premarket notification procedures in subpart E of

part 807 of this chapter subject to the limitations in § 892.9.

■ 194. In § 892.1730, revise paragraph (b) to read as follows:

§ 892.1730 Photofluorographic x-ray system.

* * * * *

(b) *Classification.* Class II (special controls). A discography kit intended for use with a photofluorographic x-ray system only is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 195. In § 892.1820, revise paragraph (b) to read as follows:

§ 892.1820 Pneumoencephalographic chair.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 196. In § 892.1850, revise paragraph (b) to read as follows:

§ 892.1850 Radiographic film cassette.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 197. In § 892.1860, revise paragraph (b) to read as follows:

§ 892.1860 Radiographic film/cassette changer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 198. In § 892.1870, revise paragraph (b) to read as follows:

§ 892.1870 Radiographic film/cassette changer programmer.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 199. In § 892.1900, revise paragraph (b) to read as follows:

§ 892.1900 Automatic radiographic film processor.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 200. In § 892.2030, revise paragraph (b) to read as follows:

§ 892.2030 Medical image digitizer.

* * * * *

(b) *Classification.* Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std.). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 201. In § 892.2040, revise paragraph (b) to read as follows:

§ 892.2040 Medical image hardcopy device.

* * * * *

(b) *Classification.* Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

■ 202. In § 892.5730, revise paragraph (b) to read as follows:

§ 892.5730 Radionuclide brachytherapy source.

* * * * *

(b) *Classification.* Class II (special controls). A prostate seeding kit intended for use with a radionuclide brachytherapy source only is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 892.9.

Dated: December 13, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–27394 Filed 12–27–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 225

[Docket ID: DOD–2019–OS–0131]

RIN 0790–AK92

Commissary Credit and Debit Card User Fee

AGENCY: Department of Defense (DoD).

ACTION: Interim final rule.

SUMMARY: This rule implements Section 621 of the John S. McCain National

Defense Authorization Act for Fiscal Year 2019 expanding patronage for commissary, exchange, and revenue-generating morale, welfare, and recreation (MWR) facilities. As part of DOD's implementation the Department is required to collect a user fee when these new populations utilize a credit or debit card that creates a cost to the Department of the Treasury for processing these transactions. As it related to this Section, such costs are only generated by credit or debit card transactions at Defense Commissary Agency (DeCA) facilities.

DATES: *Effective date:* This interim final rule is effective on December 30, 2019.

Comment date: Comments will be received by February 28, 2020.

Applicability date: Per the deadline in the statute and as implemented in this rule, these user fees go into effect on January 1, 2020.

ADDRESSES: You may submit comments, identified by docket number and or Regulatory Information Number (RIN) and title, by any of the following methods:

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

- *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number or RIN. The general policy for comments and other submissions from members of the public is to make these submissions available at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Jane Westbay, (571) 372–6579, Jane.A.Westbay.civ@mail.mil.

SUPPLEMENTARY INFORMATION:

Summary of New and Amendatory Regulatory Provisions and Their Impact

This rule implements Section 621 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Purple Heart and Disabled Veterans Equal Access Act of 2018), codified at Section 1065 of Title 10, United States Code. Section 621 expands patronage for commissary, exchange, and revenue-generating morale, welfare, and recreation (MWR) facilities. By January 1, 2020, the Department of Defense is directed to: