VOR MON PROGRAM—PHASE 2 CANDIDATE DISCONTINUANCE LIST (FY2021–FY2025)—Continued

ID	VOR Name	City	ST
PSM	PEASE	PORTSMOUTH	NH
PTW	POTTSTOWN	POTTSTOWN	PA
PUT	PUTNAM	PUTNAM	CT
PWL	PAWLING	POUGHKEEPSIE	NY
REC	REVLOC	REVLOC	PA
RKA	ROCKDALE	ROCKDALE	NY
ROA*	ROANOKE	ROANOKE	VA
SBY	SALISBURY	SALISBURY	MD
SFK	STONYFORK	STONYFORK	PA
SLT	SLATE RUN	SLATE RUN	PA
STW	STILLWATER	STILLWATER	NJ
SUG	SUGARLOAF MOUNTAIN	ASHEVILLE	NC
SWL	SNOW HILL	SNOW HILL	MD
TAY*	TAYLOR	TAYLOR	FL
TDT	TIDIOUTE	TIDIOUTE	PA
TEB	TETERBORO	TETERBORO	NJ
TGE*	TUSKEGEE	TUSKEGEE	AL
THS	ST THOMAS	ST THOMAS	PA
TRV	TREASURE	VERO BEACH	FL
UCA	UTICA	UTICA	NY
ULW	ELMIRA	ELMIRA	NY
VAN	VANCE	VANCE	SC
YRK	YORK	YORK	KY

Issued in Washington, DC, on July 19, 2016.

Leonixa Salcedo,

VOR MON Program Manager, AJM–324.

[FR Doc. 2016–17579 Filed 7–25–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

RIN 1290–AA31

Department of Labor Federal Civil Penalties Inflation Adjustment Act Catch-Up Adjustments; Correction

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Interim final rule; correction.

SUMMARY: The U.S. Department of Labor (DOL) is correcting an interim final rule published in the **Federal Register** on July 1, 2016 (81 FR 43430). The interim final rule adjusts the amounts of civil penalties assessed or enforced in its regulations pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990 as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015. That document inadvertently provided an incorrect authority citation when revising the general authority section for 20 CFR part 655. This document corrects the interim final rule by revising the appropriate authority section.

DATES: *Effective Date:* August 1, 2016.

FOR FURTHER INFORMATION CONTACT: Pamela Peters, Program Analyst, U.S. Department of Labor, Room S–2312, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–5959 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: DOL published a document in the **Federal Register** on July 1, 2016 (81 FR 43430), which made inadvertent revisions to the authority citation for part 655.

In FR Doc. 2016–15378, published on July 1, 2016, (81 FR 43430), make the following correction:

PART 655—TEMPORARY EMPLOYMENT OF FOREIGN WORKERS IN THE UNITED STATES [Corrected]

■ 1. On page 43448, in the second and third columns, in part 655—Temporary Employment of Foreign Workers in the United States, the general authority citation is corrected to read as follows:

Authority: Section 655.0 issued under 8 U.S.C. 1101(a)(15)(E)(iii), 1101(a)(15)(H)(i) and (ii), 8 U.S.C. 1103(a)(6), 1182(m), (n) and (t), 1184(c), (g), and (j), 1188, and 1288(c) and (d); sec. 3(c)(1), Pub. L. 101–238, 103 Stat. 2099, 2102 (8 U.S.C. 1182 note); sec. 221(a), Pub. L. 101–649, 104 Stat. 4978, 5027 (8 U.S.C. 1184 note); sec. 303(a)(8), Pub. L. 102–232, 105 Stat. 1733, 1748 (8 U.S.C. 1101 note); sec. 323(c), Pub. L. 103–206, 107 Stat. 2428; sec. 412(e), Pub. L. 105–277, 112 Stat. 2681 (8 U.S.C. 1182 note); sec. 2(d), Pub. L. 106–95, 113 Stat. 1312, 1316 (8 U.S.C. 1182 note); 29 U.S.C. 49k; Pub. L. 107–296, 116 Stat. 2135, as amended; Pub. L. 109–423, 120 Stat. 2900; 8 CFR 214.2(h)(4)(i); and 8 CFR 214.2(h)(6)(iii).

Subpart A issued under 8 CFR 214.2(h).

Subpart B issued under 8 U.S.C. 1101(a)(15)(H)(ii)(a), 1184(c), and 1188; and 8 CFR 214.2(h).

Subparts F and G issued under 8 U.S.C. 1288(c) and (d); sec. 323(c), Pub. L. 103–206, 107 Stat. 2428; and 28 U.S.C. 2461 note, Pub. L. 114–74 at section 701.

Subparts H and I issued under 8 U.S.C. 1101(a)(15)(H)(i)(b) and (b)(1), 1182(n) and (t), and 1184(g) and (j); sec. 303(a)(8), Pub. L. 102–232, 105 Stat. 1733, 1748 (8 U.S.C. 1101 note); sec. 412(e), Pub. L. 105–277, 112 Stat. 2681; 8 CFR 214.2(h); and 28 U.S.C. 2461 note, Pub. L. 114–74 at section 701.

Subparts L and M issued under 8 U.S.C. 1101(a)(15)(H)(i)(c) and 1182(m); sec. 2(d), Pub. L. 106–95, 113 Stat. 1312, 1316 (8 U.S.C. 1182 note); Pub. L. 109–423, 120 Stat. 2900; and 8 CFR 214.2(h).

Signed at Washington, DC this 20th day of July, 2016.

Thomas E. Perez,

Secretary, U.S. Department of Labor.

[FR Doc. 2016–17552 Filed 7–25–16; 8:45 am]

BILLING CODE 4510–HL–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, and 558

[Docket No. FDA–2014–N–0002]

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for 57 approved new animal drug applications (NADAs) and 14 approved abbreviated new animal drug applications (ANADAs) from Elanco Animal Health, A Division of Eli Lilly & Co. to Elanco US, Inc.

DATES: This rule is effective July 26, 2016.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–0571, *steven.vaughn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285 has informed FDA that it has transferred ownership of, and all rights and interest in, the 71 approved NADAs and ANADAs in table 1 to Elanco US, Inc., 2500 Innovation Way, Greenfield, IN 46140.

TABLE 1—NADAS AND ANADAS TRANSFERRED FROM ELANCO ANIMAL HEALTH, A DIVISION OF ELI LILLY & CO. TO ELANCO US, INC.

File No.	Product name	21 CFR Section
010–918	HYGROMIX 8 (hygromycin B) Type A medicated article	558.274
011–948	HYGROMIX 2.4 (hygromycin B) Type A medicated article	558.274
012–491	TYLAN 100 (tylosin) Injection	522.2640
012–548	TYLAN (tylosin phosphate)/HYGROMIX (hygromycin B)	558.274
012–965	TYLAN (tylosin) Injection	522.2640
013–076	TYLAN (tylosin tartrate) Soluble Powder	520.2640
013–162	TYLAN Premix No. 10 (tylosin phosphate) Type A medicated article	558.625
013–388	TYLAN (tylosin phosphate)/HYGROMIX (hygromycin B)	558.274
015–166	TYLAN 100 Premix (tylosin phosphate) Type A medicated article	558.625
038–878	COBAN 45, 60, 90, 110 (monensin) Type A medicated article	558.355
041–275	TYLAN 40 Sulfa-G (tylosin phosphate and sulfamethazine) Type A medicated article	558.630
047–933	COBAN (monensin)/BACIFERM (bacitracin Zn)	558.355
049–463	COBAN (monensin)/BMD (bacitracin methylenedisalicyclate)	558.355
095–735	RUMENSIN 80 and 90 (monensin) Type A medicated article	558.355
104–646	RUMENSIN (monensin)/TYLAN (tylosin phosphate)	558.355
106–964	APRALAN (apramycin sulfate) Soluble Powder	520.110
110–315	COMPONENT E–C or E–S (progesterone and estradiol benzoate) with TYLAN	522.1940
115–732	STRESNIL (azaperone) Injection	522.150
118–123	COMPUDOSE 200 (estradiol); ENCORE (COMPUDOSE 400)	522.840
118–980	MONTEBAN (narasin) Type A medicated article	558.363
126–050	APRALAN 75 (apramycin sulfate) Soluble Powder	520.110
127–507	TYLAN 5, 10, 20, 40 Sulfa-G (tylosin phosphate and sulfamethazine) Type A medicated article	558.630
130–736	COBAN (monensin) Type A medicated article	558.355
135–468	Nicarbazin Type A medicated article	558.366
135–906	COMPONENT E–H (estradiol benzoate and testosterone propionate) with TYLAN	522.842
138–952	MAXIBAN (narasin and nicarbazin) Type A medicated article	558.366
140–863	PAYLEAN 9 and 45 (ractopamine HCl) Type A medicated article	558.500
140–872	POSILAC (sometribove Zn) Injectable Suspension	522.2112
140–926	BMD (bacitracin methylenedisalicyclate)/MAXIBAN (narasin and nicarbazin)	558.366
140–929	MICOTIL 300 (tilmicosin phosphate) Injectable Solution	522.2471
140–937	BMD (bacitracin methylenedisalicyclate)/COBAN (monensin)	558.355
140–942	FLAVOMYCIN (bambermycins)/MAXIBAN (narasin and nicarbazin)	558.366
140–947	LINCOMIX (lincomycin HCl)/MAXIBAN (narasin and nicarbazin)	558.366
140–955	COBAN (monensin)/FLAVOMYCIN (bambermycins)	558.355
141–064	PULMOTIL 90 (tilmicosin phosphate) Type A medicated article	558.618
141–277	COMFORTIS (spinosad) Tablets	520.2130
141–298	SUROLAN (miconazole nitrate, polymyxin B sulfate, prednisolone acetate) Otic Suspension	524.1445
141–321	TRIFEXIS (spinosad and milbemycin oxime) Tablets	520.2134
141–110	COBAN (monensin)/STAFAC (virginiamycin)	558.355
141–164	COBAN (monensin)/TYLAN (tylosin phosphate)	558.355
141–170	MONTEBAN (narasin)/TYLAN (tylosin phosphate)	558.363
141–172	PAYLEAN (ractopamine HCl)/TYLAN (tylosin phosphate)	558.500
141–198	TYLAN (tylosin phosphate)/BIO–COX (salinomycin sodium)	558.550
141–221	OPTAFLEXX 45 (ractopamine HCl) Type A medicated article	558.500
141–224	OPTAFLEXX (ractopamine HCl)/RUMENSIN (monensin)/TYLAN (tylosin phosphate)	558.500
141–225	OPTAFLEXX (ractopamine HCl) RUMENSIN (monensin)	558.500
141–234	OPTAFLEXX (ractopamine HCl)/RUMENSIN (monensin)/MGA (melengestrol acetate)	558.500
141–290	TOPMAX 9 (ractopamine HCl) Type A medicated article	558.500
141–233	OPTAFLEXX (ractopamine HCl)/RUMENSIN (monensin)/TYLAN (tylosin phosphate)/MGA (melengestrol acetate).	558.500
141–301	TOPMAX (ractopamine HCl)/COBAN (monensin)	558.500
141–337	RECUVYA (fentanyl) Topical Solution	524.916
141–340	SKYCIS 100 (narasin) Type A medicated article	558.363
141–343	PULMOTIL 90 (tilmicosin phosphate)/RUMENSIN 90 (monensin)	558.618
141–361	PULMOTIL AC (tilmicosin phosphate) Concentrate Solution	520.2471
141–392	IMPRESTOR (pegbovigrastim) Injection	522.1684
141–438	KAVAULT (avilamycin) Type A medicated article	558.68
141–439	INTEPRITY (avilamycin) Type A medicated article	558.68

TABLE 1—NADAS AND ANADAS TRANSFERRED FROM ELANCO ANIMAL HEALTH, A DIVISION OF ELI LILLY & CO. TO ELANCO US, INC.—Continued

File No.	Product name	21 CFR Section
200–221	COMPONENT TE–G (trenbolone acetate and estradiol); COMPONENT TE–G with TYLAN; COMPONENT TE–ID with TYLAN; COMPONENT TE–IS; COMPONENT TE–IS with TYLAN; COMPONENT TE–S; COMPONENT TE–S with TYLAN.	522.2477
200–224	COMPONENT T–H (trenbolone acetate) with TYLAN; COMPONENT T–S with TYLAN	522.2476
200–343	HEIFERMAX 500 (melengestrol acetate) Type A medicated article	558.342
200–346	COMPONENT TE–200 (trenbolone acetate and estradiol); COMPONENT TE–200 with TYLAN; COMPONENT TE–H; COMPONENT TE–H with TYLAN, COMPONENT TE–H.	522.2477
200–375	HEIFERMAX 500 (melengestrol acetate)/RUMENSIN (monensin)/TYLAN (tylosin phosphate)	558.342
200–422	HEIFERMAX 500 (melengestrol acetate) Liquid Premix/RUMENSIN (monensin)	558.342
200–424	HEIFERMAX (melengestrol acetate)/OPTAFLEXX (ractopamine HCl)/RUMENSIN (monensin)/TYLAN (tylosin phosphate).	558.342
200–427	HEIFERMAX 500 (melengestrol acetate) Liquid Premix/TYLAN (tylosin phosphate)	558.342
200–430	HEIFERMAX 500 (melengestrol acetate) Liquid Premix/BOVATEC (lasalocid)/TYLAN (tylosin phosphate).	558.342
200–448	HEIFERMAX 500 (melengestrol acetate)/OPTAFLEXX (ractopamine HCl)/RUMENSIN (monensin)	558.500
200–451	HEIFERMAX 500 (melengestrol acetate)/BOVATEC (lasalocid)	558.342
200–479	HEIFERMAX 500 (melengestrol acetate)/ZILMAX (zilpaterol)/RUMENSIN (monensin)	558.665
200–480	HEIFERMAX 500 (melengestrol acetate)/ZILMAX (zilpaterol)/RUMENSIN (monensin)/TYLAN (tylosin phosphate).	558.665
200–483	HEIFERMAX 500 (melengestrol acetate)/ZILMAX (zilpaterol)	558.665

Accordingly, the Agency is amending the regulations in 21 CFR parts 520, 522, 524, and 558 to reflect these changes of sponsorship.

Following these changes of sponsorship, Elanco Animal Health, A Division of Eli Lilly & Co. is no longer the sponsor of any approved application. Accordingly, the regulations are being amended to remove this firm from the lists of sponsors of approved applications in 21 CFR 510.600(c).

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 524

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 524, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for ''Elanco Animal Health, A Division of Eli Lilly & Co.''; and in the table in paragraph (c)(2), remove the entry for ''000986''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.110 [Amended]

■ 4. In § 520.110, in paragraph (b), remove ''000986'' and in its place add ''058198''.

§ 520.2130 [Amended]

■ 5. In § 520.2130, in paragraph (b), remove ''000986'' and in its place add ''058198''.

§ 520.2134 [Amended]

■ 6. In § 520.2134, in paragraph (b), remove ''000986'' and in its place add ''058198''.

§ 520.2471 [Amended]

■ 7. In § 520.2471, in paragraph (b), remove ''000986'' and in its place add ''058198''.

§ 520.2640 [Amended]

■ 8. In § 520.2640, in paragraph (b)(1), remove ''000986'' and in its place add ''058198''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 9. The authority citation for part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.150 [Amended]

■ 10. In § 522.150, in paragraph (b), remove ''000986'' and in its place add ''058198''.

§ 522.840 [Amended]

■ 11. In § 522.840, in paragraph (b), remove ''000986'' and in its place add ''058198''.

§ 522.842 [Amended]

■ 12. In § 522.842, in paragraph (a)(2), remove ''000986'' and in its place add ''058198''.

§ 522.1684 [Amended]

■ 13. In § 522.1684, in paragraph (b), remove ''000986'' and in its place add ''058198''.

§ 522.1940 [Amended]

■ 14. In § 522.1940, in paragraph (a)(2), remove ''000986'' and in its place add ''058198''.

§ 522.2112 [Amended]

■ 15. In § 522.2112, in paragraph (b), remove ''000986'' and in its place add ''058198''.

§ 522.2471 [Amended]

■ 16. In § 522.2471, in paragraph (b), remove ''000986'' and in its place add ''058198''.

§ 22.2476 [Amended]

■ 17. In § 522.2476, in paragraph (a)(1), remove ''021641'' and in its place add ''058198''.

§ 522.2477 [Amended]

■ 18. In § 522.2477, in paragraph (b)(1), remove ''000986'' and in its place add ''058198''.

§ 522.2640 [Amended]

■ 19. In § 522.2640, in paragraph (b)(1), remove ''000986'' and in its place add ''058198''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 20. The authority citation for part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.916 [Amended]

■ 21. In § 524.916, in paragraph (b), remove ''000986'' and in its place add ''058198''.

§ 524.1445 [Amended]

■ 22. In § 524.1445, in paragraph (b), remove ''000986'' and in its place add ''058198''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 23. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

§ 558.68 [Amended]

■ 24. In § 558.68, in paragraph (b), remove ''000986'' and in its place add ''058198''.

§ 558.274 [Amended]

■ 25. In § 558.274, in paragraph (a)(1), remove ''000986'' and in its place add ''058198''; and in paragraphs (c)(1)(i) and (ii) and (c)(2)(i) and (ii), in the ''Sponsor'' column, remove ''000986'' and in its place add ''058198''.

§ 558.342 [Amended]

■ 26. In § 558.342, in paragraph (b)(2), remove ''000986'' and in its place add ''058198''; and in paragraphs (e)(1)(i) through (iv) and (e)(1)(ix) and (x), in the ''Sponsor'' column, remove ''000986'' and in its place add ''058198''.

§ 558.355 [Amended]

■ 27. In § 558.355, in paragraphs (b)(1) and (2), (b)(4) through (9), (b)(11) and (12), and (b)(14), in paragraphs (f)(1)(xiii)(*b*), (f)(1)(xxi)(*b*), (f)(1)(xxii)(*b*), (f)(1)(xxviii)(*b*), (f)(1)(xxix)(*b*), (f)(1)(xxxi)(*b*), paragraphs (f)(3)(i)(*b*)(*2*)(*iii*), (f)(3)(ii)(*b*), (f)(3)(xii)(*b*), in paragraphs (f)(4)(ii)(*b*) and (f)(4)(iii)(*b*), and in paragraph (f)(6)(i)(*b*)(*2*)(*iii*), remove ''000986'' and in its place add ''058198''.

§ 558.363 [Amended]

■ 28. In § 558.363, in paragraphs (a)(1), (3), and (8), and in paragraphs (d)(1)(ii)(B), (d)(1)(iii)(B), (d)(1)(iv)(B), (d)(1)(v)(B), and (d)(1)(vi)(B), remove ''000986'' and in its place add ''058198''.

§ 558.366 [Amended]

■ 29. In § 558.366, in paragraph (b), remove ''000986'' and in its place add ''058198''; and in paragraph (d), in the six row entries beginning in the ''Nicarbazin in grams per ton'' column with ''27 to 45'', in the ''Limitations'' and ''Sponsor'' columns, remove ''000986'' wherever it occurs and in its place add ''058198''.

§ 558.500 [Amended]

■ 30. In § 558.500, in paragraph (b), remove ''000986 and 054771'' and in its place add ''054771 and 058198''; and in paragraphs (e)(1)(i) through (iv) and (e)(2)(i) through (xiii), in the ''Limitations'' and ''Sponsor'' columns, remove ''000986'' wherever it occurs and in its place add ''058198''; and in paragraphs (e)(3)(i) through (iv), in the ''Sponsor'' column, remove ''000986'' wherever it occurs and in its place add ''058198''.

§ 558.550 [Amended]

■ 31. In § 558.550, in paragraph (d)(1)(xxii)(B), remove ''000986 and 016592'' and in its place add ''016592 and 058198''.

§ 558.618 [Amended]

■ 32. In § 558.618, in paragraph (b), remove ''000986 and 016592'' and in its place add ''016592 and 058198''; and in paragraphs (e)(1)(i) and (e)(2)(i) through (iii), in the ''Sponsor'' column, remove ''000986'' and in its place add ''058198''.

§ 558.625 [Amended]

■ 33. In § 558.625, in paragraph (b)(1), remove ''To 000986'' and in its place add ''No. 058198''.

§ 558.630 [Amended]

■ 34. In § 558.630, in paragraph (b)(1), remove ''000986'' and in its place add ''058198''.

§ 558.665 [Amended]

■ 35. In § 558.665, in paragraphs (e)(2), (3), (4), (5), (6), (8), (10), (11), and (12), in the ''Limitations'' column, remove ''000986'' wherever it occurs and in its place add ''058198''; and in paragraphs (e)(2), (3), (4), and (6), in the ''Sponsor'' column, remove ''000986'' and in its place add ''058198''.

Dated: July 20, 2016.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2016–17501 Filed 7–25–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2000–N–0158]

Physical Medicine Devices; Reclassification of Iontophoresis Device Intended for Any Other Purposes

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify iontophoresis devices intended for any other purposes, which are preamendments class III devices (regulated under product code EGJ), into class II (special controls) and to amend the device identification to clarify that devices intended to deliver specific drugs are not considered part of this regulatory classification.

DATES: This order is effective on July 26, 2016.

FOR FURTHER INFORMATION CONTACT: Jismi Johnson, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1524, Silver Spring, MD 20993, 301–796–6424, *jismi.johnson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act