and are on schedule to make the final selection. In addition, on March 12, 2001, the Linkage Plan participants filed an amendment to the Linkage Plan to conform the Linkage Plan to the minimum requirements set forth by the Commission in adopting Rule 11Ac1–7 and therefore, to allow broker-dealers effecting transactions on their markets to be eligible for an exemption from the disclosure requirements of Rule 11Ac1–7 once implementation is completed. In a letter dated February 20, 2001, the Securities Industry Association requested, on behalf of its member firms, that the Commission extend the compliance date of the rule.[5]

Because the Commission believes that options exchanges have continued to make substantial progress towards implementing a linkage, it is extending the compliance date of Rule 11Ac1–7 for six months, to October 1, 2001. The extension is intended to allow the options markets to make a final selection of the vendor to build the linkage, and provide the options exchanges with time to integrate their internal systems into the linkage system, once built. The Commission believes that good cause exists to extend the compliance date so that the options markets can implement a linkage before imposing the disclosure requirements of the Rule on broker-dealers.

The Commission finds, in accordance with Section 553(b)(3)(A) of the Administrative Procedures Act,[6] that extending the compliance date relates solely to agency organization, procedure, or practice, and does not relate to a substantive rule. Accordingly, notice, opportunity for public comment, and publication prior to the extension is unnecessary.

By the Commission.

Dated: March 15, 2001.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01–7008 Filed 3–20–01; 8:45 am]

BILLING CODE 8010–01–P

[5] *See* letter from Marc E. Lackritz, President, Securities Industry Association, to Annette Nazareth, Director, Division of Market Regulation, Commission, dated February 20, 2001 (explaining the difficulty broker-dealers face in their efforts to comply with Rule 11Ac1–7 before an options linkage is fully implemented).

[6] 5 U.S.C. 553(b)(3)(A).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 382

[Docket No. RM00–7–001; Order No. 641–A]

Revision of Annual Charges Assessed to Public Utilities

March 15, 2001.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Order Denying Rehearing and Granting Clarification in Part.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is denying rehearing and granting clarification in part of its order amending its regulations to establish a new methodology for the assessment of annual charges to public utilities. Under this new methodology, annual charges will be assessed to public utilities that provide transmission service based on the volume of electricity transmitted by those public utilities. In effect, the Commission will assess annual charges on transmission rather than on both power sales and transmission.

EFFECTIVE DATE: This Order Denying Rehearing and Granting Clarification in Part will become effective on March 15, 2001.

FOR FURTHER INFORMATION CONTACT:

Herman Dalgetty (Technical Information), Office of the Executive Director and Chief Financial Officer, 888 First Street, N.E., Washington, D.C. 20426, (202) 219–2918.

Lawrence R. Greenfield (Legal Information), Office of the General Counsel, 888 First Street, N.E., Washington, D.C. 20426, (202) 208–0415.

SUPPLEMENTARY INFORMATION:

Order Denying Rehearing and Granting Clarification in Part

Issued March 15, 2001.

I. Introduction

In an effort to reflect changes in the electric industry and in the way the Federal Energy Regulatory Commission (Commission) regulates the electric industry, in Order No. 641,[1] the Commission amended its regulations to establish a new methodology for the assessment of annual charges to public utilities. Under the new regulations, annual charges will be assessed to public utilities that provide transmission service based on the volume of electricity they transmit. The new regulations will result in the Commission's assessing annual charges on transmission rather than, as previously, assessing annual charges on both power sales and transmission.

On November 27, 2000, Public Service Electric and Gas Company (PSE&G) filed a request for rehearing of Order No. 641, and, separately, the California Independent System Operator Corporation filed a motion for clarification of Order No. 641. As discussed below, rehearing will be denied, and clarification will be granted in part.

II. Background

A. Commission Authority

The Commission is required by section 3401 of the Omnibus Budget Reconciliation Act of 1986 (Budget Act)[2] to ''assess and collect fees and annual charges in any fiscal year in amounts equal to all of the costs incurred * * * in that fiscal year.''[3] The annual charges must be computed based on methods which the Commission determines to be ''fair and equitable.''[4] The Conference Report accompanying the Budget Act provides the Commission with the following guidance as to this phrase's meaning:

> [A]nnual charges assessed during a fiscal year on any person may be reasonably based on the following factors: (1) The type of Commission regulation which applies to such person such as gas pipeline or electric utility regulation; (2) the total direct and indirect costs of that type of Commission regulation incurred during such year; [5] (3) the amount of energy—electricity, natural gas, or oil—transported or sold subject to Commission regulation by such person during such year; and (4) the total volume of all energy transported or sold subject to Commission regulation by all similarly situated persons during such year.[6]

The Commission may assess these charges by making estimates based upon data available to it at the time of the assessment.[7]

[1] Revision of Annual Charges Assessed to Public Utilities, Order No. 641, 65 FR 65,757 (November 2, 2000), FERC Stats. & Regs. ¶ 31,109 (2000) (Order No. 641).

[2] 42 U.S.C. 7178.

[3] This authority is in addition to that granted to the Commission in sections 10(e) and 30(e) of the Federal Power Act (FPA). 16 U.S.C. 803(e), 823a(e).

[4] 42 U.S.C. 7178(b).

[5] The Commission is required to collect not only all its direct costs but also all its indirect expenses such as hearing costs and indirect personnel costs. *See* H.R. Rep. No. 99–1012 at 238 (1986), *reprinted in* 1986 U.S.C.C.A.N. 3868, 3883 (Conference Report); *see also* S. Rep. No. 99–348 at 56, 66 and 68 (1986).

[6] *See* Conference Report at 239 (1986 U.S.C.C.A.N. at 3884).

[7] 42 U.S.C. 7178(c).

The annual charges do not enable the Commission to collect amounts in excess of its expenses, but merely serve as a vehicle to reimburse the United States Treasury for the Commission's expenses.[8]

B. Pre-Existing Annual Charge Billing Procedure

As required by the Budget Act, the Commission's regulations provided for the payment of annual charges by public utilities.[9] The Commission intended that these electric annual charges in any fiscal year would recover the Commission's estimated electric regulatory program costs (other than the costs of regulating Federal Power Marketing Agencies (PMAs) and electric regulatory program costs recovered through electric filing fees) for that fiscal year. In the next fiscal year, the Commission would adjust its annual charges up or down, as appropriate, to eliminate any over- or under-recovery of the Commission's actual costs and to correct any over- or under-charging of any particular person.[10]

In calculating annual charges, the Commission first determined the total costs of its electric regulatory program and subtracted all PMA-related costs and electric filing fee collections to determine total collectible electric regulatory program costs. It then used the data submitted under FERC Reporting Requirement No. 582 (FERC–582) to determine the total volumes of long-term firm wholesale sales and transmission, and short-term sales and transmission and exchanges, for all assessable public utilities. The Commission divided those transaction volumes into its collectible electric regulatory program costs to determine the unit charge per megawatt-hour for each category of long-term and short-term transactions. Finally, the Commission multiplied the transaction volume in each category for each public utility by the relevant unit charge per megawatt-hour to determine the annual charges for each assessable public utility.[11]

Public utilities subject to these annual charges were required to submit FERC–582 to the Office of the Secretary by April 30 of each year.[12] The Commission issued bills for annual charges, and public utilities then were required to pay the charges within 45 days of the date on which the Commission issued the bills.[13]

C. Order No. 641

Since the issuance of Order No. 472, in 1987, the Commission explained in Order No. 641, the industry had undergone sweeping changes, and, as the landscape of the industry had changed and continued to change, the nature of the work of the Commission likewise had changed. Order No. 641 reflected these changes—changing the way in which the Commission assesses annual charges to recover its collectible electric regulatory program costs to reflect recent industry and Commission changes, by assessing annual charges to public utilities that provide transmission service based on the volumes of electric energy transmitted.[14]

III. Discussion

On rehearing of Order No. 641, PSE&G makes two arguments. Neither of these arguments, as we explain below, is persuasive. Accordingly, we will deny rehearing.

First, PSE&G argues that Order No. 641 does not collect annual charges in a ''fair and equitable'' manner. PSE&G argues that, by treating so-called unbundled retail transmission as transmission for purposes of calculating annual charges, those utilities that have unbundled their sales to their retail customers, in whole or in part, so that they are now providing unbundled retail transmission, will pay more in annual charges than those utilities that have not unbundled their sales to their retail customers. PSE&G argues that this is unfair and inequitable.[15]

The Commission finds, however, that there is nothing unfair or inequitable about this. The statutory directive found in the Budget Act is to recover the Commission's costs. Where sales of electric energy to retail customers remain bundled (*i.e.,* the power and transmission components associated with the sale of electric energy to retail customers are provided together, part and parcel, in a single, bundled package), the sale is not subject to Commission review and the Commission incurs no costs associated with its regulation; the sale is regulated by the states. Where sales of electric energy to retail customers have been unbundled (*i.e.,* the power and transmission components are provided as distinct products or services to retail customers), the transmission component—the unbundled retail transmission—is subject to Commission review and the Commission incurs costs associated with its regulation. Unbundled retail transmission is a Commission-jurisdictional transmission service, just like any other Commission-jurisdictional transmission service.[16] It is regulated by the Commission, just as any other Commission-jurisdictional transmission service is regulated by the Commission. And so it should not be excused, but instead should be included in the calculation of annual charges, just as any other Commission-jurisdictional transmission service is reflected in the calculation of annual charges.

It is certainly true that those utilities that have unbundled to a comparatively greater extent than other utilities will be assessed a comparatively greater annual charge than other utilities. That fact, however, merely reflects that they are providing comparatively more Commission-jurisdictional transmission service, and so are comparatively more subject to Commission regulation—and thus will be comparatively more responsible for the Commission's costs. They should, therefore, be assessed a comparatively greater annual charge. They are not, however, thereby being charged a ''disproportionate'' share of the Commission's costs, as PSE&G claims.[17] In addition, as we explained in Order No. 641, in the past the regulation of transmission bundled with retail power sales was done by the states, and any costs associated with such regulation would have been incurred by state regulatory commissions and would have been subject to the regulatory assessments of those commissions. Now, the regulation of transmission

[8] *Id.* at 7178(f). Congress approves the Commission's budget through annual and supplemental appropriations.

[9] 18 CFR Part 382; *see* Annual Charges Under the Omnibus Budget Reconciliation Act of 1986, Order No. 472, 52 FR 21263 and 24153 (June 5 and 29, 1987), FERC Stats. & Regs. Regulations Preambles 1986–1990 ¶ 30,746 (1987), *clarified,* Order No. 472–A, 52 FR 23650 (June 24, 1987), FERC Stats. & Regs. Regulations Preambles 1986–1990 ¶ 30,750, *order on reh'g,* Order No. 472–B, 52 FR 36013 (Sept. 25, 1987), FERC Stats. & Regs. Regulations Preambles 1986–1990 ¶ 30,767 (1987), *order on reh'g,* Order No. 472–C, 53 FR 1728 (Jan. 22, 1988), 42 FERC ¶ 61,013 (1988).

[10] 18 CFR 382.201; *see* Order No. 472, FERC Stats. & Regs. Regulations Preambles 1986–1990 at 30,612–18; *accord* Annual Charges Under the Omnibus Budget Reconciliation Act of 1986, Order No. 507, 53 FR 46445 (Nov. 17, 1985), FERC Stats. & Regs. Regulations Preambles 1986–1990 ¶ 30,839 at 31,263–64 (1988); Texas Utilities Electric Company, 45 FERC ¶ 61,007 at 61,027 (1988) (*Texas Utilities*).

[11] 18 CFR 382.201; *see* Annual Charges Under the Omnibus Budget Reconciliation Act of 1986 (Phibro Inc.), 81 FERC ¶ 61,308 at 62,424–25 (1997).

[12] 18 CFR 382.201(b)(4).

[13] *See Texas Utilities,* 45 FERC at 61,026.

[14] Order No. 641, FERC Stats. & Regs. at 31,842; *accord id.* at 31,843–56.

[15] PSE&G Rehearing at 2–5.

[16] *See* Order No. 641, FERC Stats. & Regs. at 31,849 n.51. This jurisdictional determination, made in Order No. 888, was affirmed by the District of Columbia Circuit in *Transmission Access Policy Study Group, et al.* v. *FERC,* 225 F.3d 667, 690–95 (D.C. Cir. 2000), *cert. granted,*—U.S.L.W.—(U.S. Feb. 26, 2001).

[17] PSE&G Rehearing at 3.

associated with unbundled retail power sales will be done by this Commission, and the costs of such regulation will be incurred by this Commission and will appropriately be recovered in the annual charge assessments of this Commission. So, the end result is more a shifting of costs and assessments, rather than an absolute increase.[18]

Second, PSE&G argues that, because the Commission cannot ''say exactly how the annual [charges] will be cast among regulated parties,'' [19] *i.e.,* the Commission cannot identify ''the likely impacts of its new [annual charge] allocation method on all utilities,'' [20] Order No. 641 must be reversed.[21] PSE&G is wrong on several counts, however. Preliminarily, we note that the Commission is not required, contrary to PSE&G's implication, to have perfect information before it acts.[22] Indeed, what PSE&G asks in this regard is contradicted by its own counter-proposal, for which there is no better information and no greater certainty compared to Order No. 641. PSE&G argues that the Commission should adopt ''an allocation method based on each utility's or [Regional Transmission Organization's] transmission revenue requirement,'' [23] but that approach provides no greater certainty of the effect from year to year on any individual utility than the approach adopted in Order No. 641, or, for that matter, the approach used since the late 1980's. Neither PSE&G on rehearing, nor PSE&G and the others with whom it filed in their original comments, provides any explanation or justification of how this proposed allocation method would provide greater certainty.

Moreover, PSE&G's counter-proposal would, in fact, provide no greater certainty. Just as the public utilities' transmission volumes which Order No. 641 uses change from year to year, transmission rates and the underlying transmission revenue requirements on which PSE&G would rely likewise change from year to year—as public utilities file changes in their transmission rates to reflect their changing costs. Similarly, the Commission's costs, the other piece of the annual charges equation, also change from year to year—and the Commission's costs change regardless of whether transmission volumes (per Order No. 641) or transmission revenue requirements (per PSE&G) are used to calculate the annual charge assessments.

In addition, we note that, in their original comments, PSE&G and the others with whom it filed never made the argument that PSE&G advances here—PSE&G and the others never argued that the approach proposed by the Commission must fail because the effect on individual utilities could not be ascertained with certainty in advance.

The approach taken by the Commission, and the Commission's reliance on the factors it has relied on, are, in fact, expressly authorized by the Budget Act and the accompanying Conference Report. As noted above, the Commission is required by section 3401 of the Budget Act to ''assess and collect fees and annual charges in any fiscal year in amounts equal to all of the costs incurred . . . in that fiscal year.'' [24] The Commission thus sets its annual charges to recover its costs, and, as relevant here, thus sets its electric annual charges to recover its collectible electric regulatory program costs.

The annual charges also must be computed based on methods which the Commission determines are ''fair and equitable,'' [25] and the Conference Report accompanying the Budget Act explains that the annual charges ''may be reasonably based on'' four factors:

(1) The type of Commission regulation which applies to such person such as gas pipeline or electric utility regulation; (2) the total direct and indirect costs of that type of Commission regulation incurred during such year; (3) the amount of energy—electricity, natural gas, or oil—transported or sold subject to Commission regulation by such person during such year; and (4) the total volume of all energy transported or sold subject to Commission regulation by all similarly situated persons during such year.[26]

These four factors are precisely the factors that the Commission has used in Order No. 641. Order No. 641, per factor (1), distinguishes electric regulation and its costs from gas regulation and its costs.[27] Order No. 641, per factor (2), looks at the Commission's total electric regulatory program costs, and assesses in annual charges those costs not already recovered in filing fees or from the PMAs. Most critically and most relevant here, Order No. 641, per factors (3) and (4), looks, each year, to the total amounts of electric energy transmitted by all jurisdictional public utilities in developing the per unit charge for that year, and then it looks to each individual jurisdictional public utility's transmission in assessing an annual charge to that public utility.[28]

Moreover, the Commission has consistently taken this approach. The Commission in its pre-existing annual charge regulations, adopted in Order No. 472 in the late 1980's, assessed annual charges to public utilities in each year by identifying its collectible electric regulatory program costs to be collected from those utilities, and then identifying the total volume of transactions (at that time, both power sales and transmission) over which those costs would be spread. The results were per unit charges, which the Commission then used to determine (based on each public utility's volume of transactions) the annual charges to be assessed to each public utility.[29]

This same approach is the approach that the Commission continues to employ in Order No. 641. The only difference between what the Commission did before and what the Commission will do now is in the transaction volumes used. Previously, the Commission looked to both power sales and transmission transactions (and also did separate calculations to develop separate per unit charges for long-term and short-term transactions). Now, the Commission will look to *only* transmission transactions (and also will no longer distinguish between long-term and short-term transactions—all transmission transactions, regardless of length, will be treated identically).

The California ISO does not seek rehearing of Order No. 641, but rather seeks clarification. As explained below, we will grant clarification in part.

[18] Order No. 641, FERC Stats. & Regs. at 31,851.

[19] PSE&G Rehearing at 6.

[20] *Id.* at 7.

[21] *Id.* at 5–7.

[22] United States Department of the Interior v. FERC, 952 F.2d 538, 546 (D.C. Cir. 1992) (Commission is not required ''to have perfect information before it takes any action,'' and such a requirement would be ''contrary to the statutory standard that requires [a court] to affirm any [Commission] factual finding supported by substantial evidence'' and ''[m]ore practically . . . would hamstring the agency;'' ''[v]irtually every decision must be made under some uncertainty''); *see also* City of New Martinsville, *West Virginia* v. *FERC,* 102 F.3d 567, 572 (D.C. Cir. 1996) (''We recognize that the Commission must often work with incomplete information.'').

[23] PSE&G Rehearing at 7. In the original comments cited by PSE&G, *see id.* at 7 nn.15–16, PSE&G and the others with whom it filed proposed basing annual charges ''on the relative share of the total transmission revenue requirement * * * of each transmission provider as compared to the total share of the [transmission revenue requirements] of all transmission providers.'' Comments of Atlantic City Electric Company, *et al.* at 2; *accord id.* at 6–7.

[24] *See supra* note 3 and accompanying text.

[25] *See supra* note 4 and accompanying text.

[26] *See supra* note 6 and accompanying text.

[27] *Accord* Conference Report at 238–39 (1986 U.S.C.C.A.N. at 3883–84).

[28] In fact, the Conference Report also stated that the conferees expected the Commission ''to assess annual charges proportionately on the basis of annual sales or volumes transported.'' Conference Report at 239 (1986 U.S.C.C.A.N. at 3884).

[29] *See supra* notes 9–13 and accompanying text.

The California ISO notes that, under Order No. 641, annual charge assessments can be recovered from transmission customers as a legitimate cost of providing transmission service, but that the specifics of such recovery are left to be addressed by individual public utilities in case-by-case filings with the Commission.[30] The California ISO explains that, because there is uncertainty as to the level of annual charges to be assessed against each individual public utility, and therefore uncertainty as to the design of an appropriate cost-recovery mechanism, the Commission should clarify that individual public utilities may recover annual charges in transmission rates from transmission customers even if there is some uncertainty as to the level of annual charges being assessed against those public utilities, and that annual charges assessed by the Commission may, in turn, be recovered in transmission rates in the year that the charges are billed to those public utilities (even though the annual charges assessed by the Commission are developed using data that reflects the prior year's transactions).[31] The California ISO adds that, as a revenue-neutral, not-for-profit entity that passes through all of its costs to the market participants that use the transmission system it operates, there is a special need for clarification, and that, in the first year that the new annual charge methodology is used, there is likewise a special need for clarification.[32] The California ISO also commits to modify any annual charge cost-recovery mechanism that it proposes ''as needed to prevent over- or under-recovery of such costs once it receives the initial assessment of annual charges under the new methodology.'' [33]

The Commission explained, in Order No. 641, that the purpose of Order No. 641 was to change the methodology by which the Commission assessed annual charges to public utilities, and that the issue of the rate recovery of annual charge assessments by the public utilities to whom they were assessed was a different issue and outside the scope of Order No. 641. The Commission noted that it already had in place regulations that address rate recovery of utility costs, *i.e.,* Part 35 of its regulations, but added that, to allay public utility concerns, it would state in Order No. 641 that the annual charges assessed by the Commission were ''costs that can be recovered in transmission rates as a legitimate cost of providing transmission service.'' [34]

We reaffirm those determinations here. We also note that our regulations provide great flexibility in how public utilities may develop their rates, including their transmission rates. Our regulations provide that rates may be based on data for historical periods, such as the so-called Period I test period, and that rates may also be based on data for future periods, such as the so-called Period II test period.[35] We thus have long allowed rates to be based on estimates, as long as the estimates were reasonable when made.[36] This flexibility is sufficient, we believe, to allow public utilities like the California ISO to recover in their transmission rates for the first year under the new annual charges methodology adopted in Order No. 641, *i.e.,* calendar year 2002, the annual charges that will be assessed by the Commission in that same year, *i.e.,* calendar year 2002 (even though those charges are calculated from transactions that occurred during the preceding year, calendar year 2001).[37] To this extent, therefore, we clarify Order No. 641.

The Commission Orders

PSE&G's request for rehearing is hereby denied, and the California ISO's request for clarification is hereby granted in part, as discussed in the body of this order.

By the Commission.

David P. Boergers,

Secretary.

[FR Doc. 01–7001 Filed 3–20–01; 8:45 am]

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[30] California ISO Clarification at 1–2.

[31] *Id.* at 2, 7–8, 11–13. In the alternative, the California ISO objects to Order No. 641 in the absence of additional information concerning the level of annual charges that will be assessed under Order No. 641. *Id.* at 2, 7, 8–11. As noted earlier, annual charges are intended to recover the Commission's collectible electric regulatory program costs (*i.e.,* its total electric regulatory program costs, less any electric filing fees and less the costs of regulating the PMAs). Under Order No. 641, these collectible electric regulatory program costs will now be recovered from public utilities based on transmission volumes (rather than, as in the past, both power sale and transmission volumes). To the extent that the California ISO's pleading may be construed as seeking rehearing of Order 641, its arguments are addressed in the discussion earlier concerning PSE&G's similar arguments.

[32] *Id.* at 6–7, 12.

[33] *Id.* at 12

[34] Order No. 641, FERC Stats. & Regs. at 31,857.

[35] *See* 18 CFR 35.13. *Accord, e.g.,* Revised Requirements for Filing Changes in Electric Rate Schedules, Order No. 91, 45 FR 46,352 (July 10, 1980), FERC Stats. & Regs. Regulations Preambles 1977–1981 ¶ 30,170 at 31,146–48 (1980), *reh'g denied,* Order No. 91–A, 12 FERC ¶ 61,206 (1980).

[36] *E.g.,* New England Power Company, Opinion No. 379, 61 FERC ¶ 61,331 at 62,217 & n.62 (1992), *reh'g denied,* Opinion No. 379–A, 65 FERC ¶ 61,036 (1993), *aff'd,* 53 F.3d 377, 380 (D.C. Cir. 1995); Southern California Edison Company, Opinion No. 359, 53 FERC ¶ 61,408 at 62,415 & n.22 (1990), *reh'g denied,* Opinion No. 359–A, 54 FERC ¶ 61,320 (1991).

[37] Particularly given the California ISO's commitment to modify any annual charge cost-recovery mechanism that it proposes as needed to prevent over- or under-recovery of such costs once it receives the initial assessment of annual charges under this new methodology. *See supra* note 33 and accompanying text.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 00P–1554]

Medical Device; Exemption From Premarket Notification; Class II Devices; Pharmacy Compounding Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order granting a petition requesting exemption from the premarket notification requirements for pharmacy compounding systems classified within the intravascular administration set, with certain limitations. This rule will exempt from premarket notification pharmacy compounding systems classified within the intravascular administration set and establishes a guidance document as a special control for this device. FDA is publishing this order in accordance with the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This rule is effective March 21, 2001.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Public Law 101–629)), devices are to be classified