CRI ratings, PTT significantly outperformed PET on the heaviest of the three wear cycles. Specifically, in the vast majority of trials, PET performed below an acceptable rating (*i.e.*, 3) while PTT performed at or above a 3 rating in all trials.[73] Moreover, the central tendency of each data set shows a difference of over one full interval. Second, Petitioners tested carpet weights that consumers typically purchase, whereas Invista's Vettermann Drum testing utilized heavier carpet that only a small percentage of consumers actually buy.[74] Finally, Invista's assertion that Petitioners tested PET and PTT of different fiber weights (dpf) is not at issue because Petitioners did, in fact, test the same weight PET and PTT carpet fibers.[75] Accordingly, the Petition satisfies the second criterion for granting a new generic fiber subclass name.

Third, Petitioners have demonstrated that PTT's distinctive properties are of importance to the general public. As discussed earlier, Mohawk's consumer survey shows that consumers shopping for carpet consider durability/resiliency to be very important attributes. Specifically, a 2004 study that Mohawk commissioned found that 67% of respondents rated carpet durability/resiliency as a very important trait. Thus, the Petition satisfies the third criterion for granting a new generic fiber subclass name.

Finally, PTT's enhanced durability is the result of substantially differentiated physical characteristics. Specifically, Petitioners explained that the molecular structure of PTT is more coil-like than PET's straight-wire structure. Thus, PTT fibers are better able to recover without permanently deforming and developing a crushed appearance.[76] The Commission's textile expert reviewed the material that Petitioners submitted and confirmed this fact.[77] Accordingly, the Petition satisfies the final criterion for granting a new generic fiber subclass name.

Because the Petition meets all the criteria for establishing a new generic subclass fiber name, the Commission amends Rule 7(c) to define the generic subclass ''triexta'' and to allow use of the name ''triexta'' as an alternative to the generic name ''polyester'' for PTT fiber.[78] Because ''triexta'' is the second subclass generic designation for ''polyester,'' we have moved the first subclass designation to its own subsection, (c)(1), for clarity. Finally, based on this decision, the temporary designation ''PTT001'' is revoked as of the effective date of this amendment.

[73] Petition at 14-15.

[74] Invista also submitted the results of several other tests purporting to show that PTT does not perform significantly better than PET. *See supra* note 37. The record does not indicate that any of these tests are current or former industry standard tests. In addition, some of them involved heavier weight PET and PTT carpet than the weight of carpet consumers typically purchase and, for others, the record does not indicate the weight of the carpets tested. Therefore, we accord these test results less weight.

[75] DuPont #535294-00017 at 13.

[76] Petition at 7-8.

[77] Expert Report.

[78] The Commission has selected the name ''triexta'' because it was the one subclass name proposed by Petitioners to which no commenter objected.

[79] 72 FR 48600 (Aug. 24, 2007).

VI. Effective Date

The Commission is making the amendment effective today, March 26, 2009, as permitted by 5 U.S.C. 553(d), because the amendment does not create new obligations under the Textile Rules; rather, it merely creates a fiber name and definition that covered companies may use to comply with the Textile Rules.

VII. Regulatory Flexibility Act

In the Request for Public Comment,[79] the Commission tentatively concluded that the provisions of the Regulatory Flexibility Act relating to an initial regulatory analysis, 5 U.S.C. 603-604, did not apply to the Petition's proposal because the amendment, if promulgated, would not have a significant economic impact on a substantial number of small entities. The Commission believed that the proposed amendment would impose no additional obligations, penalties, or costs. The amendment simply would allow covered companies to use a new generic name as an alternative to an existing generic name for that defined subclass of fiber, and would impose no additional labeling requirements. To ensure, however, that the Commission did not overlook any substantial economic impact, the Commission solicited public comment in the Request for Public Comment on the effects of the proposed amendment on costs, profits, competitiveness of, and employment in small entities.

The Commission did not receive any comment in response. Accordingly, the Commission hereby certifies, pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605(b), that the amendment promulgated today will not have a significant economic impact on a substantial number of small entities.

VIII. Paperwork Reduction Act

This amendment does not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995, Pub. L. 104-13, 109 Stat. 163, 44 U.S.C. chapter 35 (as amended), and its implementing regulations, 5 CFR 1320 *et seq.* Those procedures for establishing generic names that do constitute collections of information, 16 CFR 303.8, have been submitted to OMB, which has approved them and assigned them control number 3084-0101.

List of Subjects in 16 CFR Part 303

Labeling, Textile, Trade practices.

IX. PART 303—RULES AND REGULATIONS UNDER THE TEXTILE FIBER PRODUCTS IDENTIFICATION ACT

■ 1. The authority citation for part 303 continues to read as follows:

Authority: Sec. 7(c) of the Textile Fiber Products Identification Act (15 U.S.C. 70e(c)).

■ 2. In § 303.7, in paragraph (c), designate the second sentence, which follows the second chemical description, as paragraph (c)(1) and add new paragraph (c)(2) to read as follows:

§ 303.7 Generic names and definitions for manufactured fibers.

* * * * *

(c) * * *

(2) Where the glycol used to form the ester consists of at least ninety mole percent 1,3-propanediol, the term ''*triexta*'' may be used as a generic description of the fiber.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. E9–6633 Filed 3–25–09: 8:45 am]

BILLING CODE 6750–01–S

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 42

[Docket No. RM06–8–002; Order No. 681–B]

Long-Term Firm Transmission Rights in Organized Electricity Markets

Issued March 20, 2009.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule; order on rehearing and clarification.

SUMMARY: The Federal Energy Regulatory Commission is issuing an order on rehearing and clarification of *Long-Term Firm Transmission Rights in Organized Electricity Markets*, Order No. 681–A, 71 FR 68,440 (November 16,

2006). The order on rehearing affirms, with certain clarifications, the fundamental determinations made in Order No. 681, as clarified by Order No. 681–A.

DATES: *Effective Date:* Order No. 681 became effective on August 31, 2006. This order on rehearing and clarification will become effective April 27, 2009.

FOR FURTHER INFORMATION CONTACT: Roland Wentworth (Technical Information), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8262.

Michael P. McLaughlin (Technical Information), Office of Energy Market Regulation, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–6135.

Heidi Werntz (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8910.

Richard Wartchow (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8744.

SUPPLEMENTARY INFORMATION:

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I. Introduction

1. In this order we affirm, with certain clarifications, the fundamental determinations made in Order Nos. 681 and 681–A.[1] In Order No. 681, as reaffirmed and clarified in Order No. 681–A, the Commission required each transmission organization that is a public utility with one or more organized electricity markets to make available long-term firm transmission rights that satisfy each of seven guidelines.[2]

2. Under guideline (5), the Commission permits transmission organizations to place reasonable limits on the amount of capacity used to support long-term firm transmission rights.[3] Recognizing that ''transmission capacity is limited and the amount that can reasonably be made available for long-term transmission rights may be lesser still,'' [4] the Commission construed new section 217 of the Federal Power Act (FPA) to provide a general preference for load serving entities to obtain transmission service.[5] On rehearing, in discussing priority when transmission capacity is limited, the Commission declined to draw a broad conclusion that it would always be unreasonable for a transmission organization to treat external and internal load serving entities differently in allocating long-term firm transmission rights.[6] Three parties filed requests for clarification or, in the alternative, rehearing of Order Nos. 681 and 681–A, focusing primarily on issues associated with the allocation of long-term firm transmission rights to load serving entities serving load located outside the transmission organization (external load serving entities). Rehearing was also requested on the Commission's determination that the statute does not require a hedge for marginal loss charges.

3. In this order, we grant certain clarifications concerning allocation of long-term firm transmission rights to external load serving entities and deny requests for rehearing.

II. Background

A. Energy Policy Act of 2005

4. On August 8, 2005, EPAct 2005 [7] was signed into law. Section 1233 of EPAct 2005 added a new section to the FPA, section 217, which provides:

> The Commission shall exercise the authority of the Commission under this Act in a manner that facilitates the planning and expansion of transmission facilities to meet the reasonable needs of load-serving entities to satisfy the service obligations of the load-serving entities, and enables load-serving entities to secure firm transmission rights (or equivalent tradable or financial rights) on a long-term basis for long-term power supply arrangements made, or planned, to meet such needs.[8]

The statute further required the Commission to implement section 217 of the FPA within one year of the effective date of EPAct 2005.[9]

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[1] *Long-Term Firm Transmission Rights in Organized Electricity Markets*, Order No. 681, 71 FR 43,564 (Aug. 1, 2006), FERC Stats. & Regs. ¶ 31,226, *reh'g denied*, Order No. 681–A, 117 FERC ¶ 61,201 (2006).

[2] Order No. 681, FERC Stats. & Regs. ¶ 31,226 at P 1, 23; Order No. 681–A, 117 FERC ¶ 61,201 at P 1.

[3] Order No. 681, FERC Stats. & Regs. ¶ 31,226 at P 318.

[4] *Id.* P 320.

[5] Order No. 681, FERC Stats. & Regs. ¶ 31,226 at P 318 (construing EPAct 2005, section 217; Pub. L. 109–58, § 1233, 119 Stat. 594, 957 (2005); 16 U.S.C. 824q (2006)).

[6] Order No. 681–A, 117 FERC ¶ 61,201 at P 81.

[7] Public Law No. 109–58, 119 Stat. 594 (2005).

[8] 16 U.S.C. 824q (2006).

[9] 119 Stat. 594, 960. ''Transmission organization'' is defined in EPAct 2005 as ''a Regional Transmission Organization, Independent System Operator, independent transmission provider, or other transmission organization finally approved by the Commission for the operation of transmission facilities.'' Public Law No. 109–58, § 1291, 119 Stat. 594, 985. In Order Nos. 681 and 681–A, we adopted this definition with slight modifications for the purposes of the Final Rule.

B. Notice of Proposed Rulemaking

5. As a first step towards implementing FPA section 217, on February 2, 2006, the Commission issued a Notice of Proposed Rulemaking (NOPR) that proposed to amend its regulations to require each transmission organization that is a public utility with one or more organized electricity markets to make available long-term firm transmission rights that satisfy guidelines established by the Commission.[10] The NOPR proposed eight guidelines, and sought comments on various issues raised by the introduction of long-term firm transmission rights in the organized electricity markets.

C. Final Rule: Order No. 681

6. On July 20, 2006, the Commission issued a Final Rule in this proceeding, Order No. 681. Consistent with EPAct 2005, in Order No. 681, the Commission required independent transmission organizations that oversee electricity markets to make available long-term firm transmission rights that satisfy each of the seven guidelines ultimately established by the Commission in that order. The Commission further directed transmission organizations subject to the Final Rule to file, no later than January 29, 2007, either: (1) Tariff sheets and rate schedules that make available long-term firm transmission rights that satisfy each of the seven guidelines; or (2) an explanation of how the transmission organization's tariff and rate schedules already provide for long-term firm transmission rights that satisfy each of the guidelines. The Commission also required entities that subsequently meet the statutory definition of transmission organization after January 29, 2007 to satisfy the requirements of the Final Rule.[11]

7. In issuing Order No. 681, the Commission explained that it sought to provide increased certainty regarding the congestion cost risks of long-term firm transmission service in organized electricity markets in order to facilitate new investments and other long-term power supply arrangements.[12] The guidelines adopted in Order No. 681 were intended to ensure that the long-term firm transmission rights made available by transmission organizations subject to the rule would support long-term power supply arrangements.[13] Moreover, the Commission emphasized that it would not compel transmission organizations to provide rights that are infeasible based on the existing system, nor would the Commission guarantee that a load serving entity will be able to obtain long-term firm transmission rights sufficient to hedge its entire resource portfolio or be able to obtain all of its requested long-term firm transmission rights.[14] Rather, the Commission concluded that transmission organizations and their stakeholders should each have flexibility to determine the level at which a load serving entity may nominate long-term firm transmission rights, as long as that level does not fall below the entity's ''reasonable needs.'' [15] By reasonable needs, the Commission meant that long-term firm transmission rights should be sufficient to hedge the congestion associated with providing baseload service.[16] Once an entity obtains long-term firm transmission rights, Order No. 681 requires these rights to be fully funded over their entire term.[17]

8. Significantly, Order No. 681 adopted guidelines rather than prescriptive requirements for long-term firm transmission rights. While transmission organizations are required to satisfy each guideline, the Commission gave them the flexibility to design long-term firm transmission rights that reflect regional preferences and accommodate regional market designs.[18]

9. Many of the rehearing requests focus on guideline (5), which gives load serving entities priority to transmission rights on the existing system:

> Load serving entities must have priority over non-load serving entities in the allocation of long-term firm transmission rights that are supported by existing capacity. The transmission organization may propose reasonable limits on the amount of existing capacity used to support long-term firm transmission rights.[19]

10. In the preamble to guideline (5), the Commission rejected the NOPR proposal for an absolute preference for load serving entities with long-term power supply arrangements.[20] Instead, the Commission opted for a general preference for load-serving entities over non-load serving entities, although transmission organizations, on a regional basis, are not precluded from giving allocation priority to holders of long-term contracts over other load serving entities when capacity is limited.[21] Further, with respect to priority of eligibility, the Commission explained that ''long-term firm transmission rights should be made available first to those entities that have an obligation to serve load within the transmission organization's service territory and are required to contribute to the embedded cost of the transmission organization's transmission system.'' [22] The Commission concluded that ''[a]ny entity that has neither an obligation to serve load on the transmission organization's transmission system, nor an obligation to pay the embedded costs of that system, should not be given a preference to acquire long-term firm transmission rights supported by the system's existing capacity.'' [23] Further, the Commission explained that ''long-term firm transmission rights must be available to all market participants.'' [24] Guideline (5) ''serves only as a 'tiebreaker' between load serving entities and non-load serving entities when existing transmission capacity is limited.'' [25]

D. Rehearing Order: Order No. 681–A

11. On rehearing, the Commission upheld its determinations in Order No. 681 and offered certain clarifications. Specifically, on the issue of priority for load serving entities with load outside the region, the Commission stated that a load serving entity should receive preference in the allocation of long-term firm transmission rights within a transmission organization's region ''only to the extent that the transmission organization plans and constructs its transmission system to support the load of the load serving entity, and the load serving entity contributes to the cost that the transmission organization incurs for that purpose.'' [26] The Commission found that it would be unreasonable to provide a preference where the load has not contributed to the system's embedded costs, and the transmission organization has not planned and built its system to accommodate the load.[27]

[10] *Long-Term Firm Transmission Rights in Organized Electricity Markets*, NOPR, 71 FR 6,693 (Feb. 9, 2006), FERC Stats. & Regs. ¶ 32,598 (2006).

[11] Order No. 681, FERC Stats. & Regs. ¶ 31,226 at P 494.

[12] *Id.* P 16.

[13] *Id.*

[14] *Id.* P 17–18.

[15] *Id.* P 323.

[16] *Id.*

[17] *Id.* P 18.

[18] *Id.* P 2. The Commission recognized the possibility that the flexible regional approach adopted in the Final Rule could create seams issues, and directed each transmission organization to explain in its compliance filing how its proposal addresses potential seams issues. *Id.* P 107.

[19] *Id.* P 325; 18 CFR 42.1(d)(5) (2008).

[20] Order No. 681, FERC Stats. & Regs. ¶ 31,226 at P 318.

[21] *Id.* P 321.

[22] *Id.* P 328.

[23] *Id.*

[24] *Id.* P 329.

[25] *Id.*

[26] Order No. 681–A, 117 FERC ¶ 61,201 at P 78.

[27] *Id.*

12. The Commission provided two examples where external load serving entities should be given a preference in the allocation of long-term firm transmission rights equivalent to the preference accorded to load serving entities with loads that lie within the transmission organization's region. First, the Commission recognized that a load serving entity that has an existing agreement with the transmission organization to pay a share of the embedded costs of the transmission system on a long-term basis to support load outside the region should be entitled to receive this preference.[28] Second, external load-serving entities should qualify for the preference where pancaked rates between the transmission organization and the other transmission provider(s) have been eliminated, as long as the agreement with the load-serving entity provides for cost sharing in accordance with the non-pancaked rates currently in effect.[29]

13. In addition, the Commission stated that, where there is no agreement between an external load serving entity and the transmission organization:

> a load serving entity with load that sinks outside the transmission organization's region is entitled to receive long-term firm transmission rights from existing system capacity to support that load to the extent that capacity is available after the needs of the load serving entities whose loads are within the region have been met. However, in such cases, we expect that the load serving entity would be required to contribute, on a long-term basis, toward the embedded cost of the transmission system, by paying either pancaked or non-pancaked rates, as applicable.[30]

14. The Commission also denied the Sacramento Municipal Utility District (SMUD) request to clarify that it would be unreasonable for a transmission organization to allocate long-term firm transmission rights based on whether load is located in the transmission organization's control area or has agreed to cede control of its transmission facilities to that organization. The Commission noted that it is not unduly discriminatory for a transmission organization to impose additional requirements on external load as a precondition to receiving such rights.[31] The Commission declined to draw a broad conclusion in a rulemaking of general applicability that it may never be reasonable to treat external load differently from internal load for purposes of allocating long-term firm transmission rights.[32]

III. Discussion

A. Procedural Matters

15. Timely requests for rehearing and/or clarification were filed by the following entities: Long Island Power Authority and its wholly-owned operating subsidiary, LIPA (LIPA), Modesto Irrigation District (Modesto), and SMUD.

B. Requests for Rehearing and/or Clarification

1. Contract With Transmission Owner Rather Than Transmission Organization

16. Modesto states that the Final Rule allowed load serving entities that pay the embedded costs of a transmission organization's system to qualify for priority in receiving long-term firm transmission rights, even if located outside of the transmission organization's control area. Modesto argues that in so doing, however, the Commission created ''an unjust and unreasonable and unduly discriminatory condition'' in that such load-serving entities must contract directly with the transmission organization, rather than with entities within the transmission organization's footprint, to pay the embedded cost of the transmission system, in order to qualify for priority in receiving long-term firm transmission rights.[33]

17. Modesto explains that it is a load serving entity located outside of and adjacent to the California Independent System Operator (CAISO). To meet its native load obligations, Modesto states that it often must wheel power over the CAISO-controlled grid from resources located inside and outside of the CAISO control area. Modesto states that one of its pre-existing arrangements through which it facilitates transmission of its electricity through the CAISO control area is with Pacific Gas & Electric Company (PG&E), a participating transmission owner of the CAISO.

18. Modesto asserts that, through its payments to PG&E, it contributes to the embedded costs of the transmission system that is under the CAISO's operational control. Modesto argues that, under Order No. 681–A, it would be denied a priority for obtaining long-term firm transmission rights because its agreement is with a participating transmission owner, PG&E, and not with the CAISO. Modesto argues that conditioning eligibility for allocation of long-term firm transmission rights on whether an agreement is with a transmission organization rather than a participant of that organization unduly discriminates against entities that are similarly situated. Specifically, Modesto complains that entities that are contributing to the embedded costs of the transmission organization's system through pre-existing arrangements with the transmission organization are unduly discriminated against, compared with entities that have pre-existing arrangements with transmission owners who have turned their transmission over to the operational control of the transmission organization.

Commission Determination

19. We grant Modesto's requested clarification. In Order No. 681–A, the Commission did not intend to restrict unnecessarily the types of contractual vehicles by which a load serving entity with load outside a transmission organization's region may demonstrate that it is entitled to receive a preference in the allocation of long-term firm transmission rights supported by the region's existing transmission capacity. The salient issue here is whether the external load serving entity has historically contributed and will continue to contribute on an ongoing basis to the embedded costs of the transmission system.[34] As long as the external load serving entity can demonstrate that it has paid and will continue to pay the embedded costs of the transmission system, the precise vehicle by which this is accomplished is not important. Thus, a commitment to pay an appropriate share of embedded costs could be achieved through a contractual agreement with the transmission organization itself, through a pre-existing agreement with one or more transmission owners that have turned operational control of their transmission system over to the transmission organization, or by some other verifiable means.[35] We further note that, while Modesto's specific contractual issue is beyond the scope of this general rulemaking proceeding, it appears to have been favorably resolved

[28] *Id.* P 79.

[29] *Id.*

[30] *Id.* P 80.

[31] *Id.* P 81 (erroneously citing *New England Power Pool*, 100 FERC ¶ 61,287, at P 85 (2002); correctly citing *Cal. Indep. Sys. Operator Corp.*, 116 FERC ¶ 61,274, at P 766 (2006) (*MRTU Order*), *order on reh'g*, 119 FERC ¶ 61,076 (2007) (*MRTU Rehearing Order*)).

[32] *Id.*

[33] Modesto Rehearing Request at 4–5.

[34] *See, e.g., New England Power Pool*, 100 FERC ¶ 61,287, at P 85 (2002).

[35] *See, e.g., PJM Interconnection, L.L.C.*, 119 FERC ¶ 61,144, at P 40 & n.34, *order on clarification*, 121 FERC ¶ 61,073 (2007) (upholding PJM's proposal to allow an external load serving entity to receive long-term firm transmission rights in stage 1A if it is a transmission customer taking and paying for firm service and if it was serving load from resources within a zone at the time that zone was integrated into PJM).

in the compliance phase of this proceeding.[36]

2. Lack of a Transmission Agreement

20. SMUD asks the Commission to clarify whether a load serving entity outside an ISO/RTO control area could qualify for an allocation priority equivalent to that of a load serving entity within the control area where its lack of an existing long-term firm service arrangement is the transmission organization's ''fault.'' [37] Asserting that this question is not purely ''academic,'' SMUD explains that it had a long-term firm transmission arrangement for more than 35 years, which, according to SMUD, lapsed due to the CAISO's delay in developing long-term firm transmission rights. Pointing out that the CAISO was initially ordered to develop long-term firm transmission rights in 1997, SMUD argues that it would have continued to have a long-term firm transmission agreement in place and would have qualified for a priority equivalent to that accorded load serving entities within the CAISO control area if the CAISO had developed those long-term rights on a timely basis.[38]

21. SMUD states that it is willing to provide assurances to the CAISO that it will continue to pay a share of the fixed costs of the transmission grid operated by the CAISO. SMUD insists that absent clarification, however, Order No. 681–A does not provide a clear opportunity for SMUD and other similarly situated load serving entities to provide such assurances.[39] SMUD asks the Commission to clarify that a load serving entity located outside an ISO/RTO control area that lacks an existing long-term firm transmission agreement can qualify for the same treatment accorded a load serving entity with an existing long-term firm transmission agreement, if it can demonstrate: (1) Its reliance on the ISO/RTO transmission grid; (2) its commitment to continue to contribute to the fixed costs of the system; and (3) that its lack of a long-term transmission agreement with the ISO/RTO was outside of its control.[40]

Commission Determination

22. We grant in part and deny in part the clarification requested by SMUD. First, we decline to adopt SMUD's three-part test for determining whether an external load serving entity should qualify for a preference in the allocation of long-term firm transmission rights.[41] However, we grant clarification regarding the broader issue SMUD raises, which is whether an external load serving entity may qualify for a preference if it contributes to the embedded cost of the regional transmission system, but is not a party to a qualifying agreement for long-term transmission service at the time of its request. We clarify that the lack of an existing long-term service agreement with the transmission organization or a participating transmission owner does not necessarily disqualify an external load serving entity from receiving a preference in the allocation of long-term firm transmission rights that are supported by the existing capacity of the transmission organization's system. If the external load serving entity has maintained a continuous service relationship with the transmission organization or transmission owner, through which it continues to contribute to the embedded costs of the transmission system for the duration of the long-term firm transmission rights it seeks, that entity may be entitled to an allocation of long-term firm transmission rights. However, the entity must also satisfy all of the other eligibility requirements of the transmission organization, and it must provide the transmission organization with appropriate assurances that it will continue to satisfy these requirements going forward.

23. With regard to the status of SMUD's long-term contractual relationship with the CAISO or any of its Participating Transmission Owners, including the question of which party may be at fault for causing a prior agreement to lapse, we note that this is a case-specific matter and, as such, is beyond the scope of this proceeding.[42]

3. Clarification of Paragraph 80 of Order No. 681–A

24. LIPA asks the Commission to clarify that, consistent with paragraph 78 of Order No. 681–A, there should be no distinction between the treatment of internal and external load serving entities when allocating long-term firm transmission rights, where the transmission organization plans and constructs its transmission system to support the external load serving entity's requirements and the load serving entity is obligated to contribute to the costs the ISO/RTO incurs for that purpose. LIPA's concern centers on paragraph 80 of Order No. 681–A, which provides that:

> in cases where [an external load serving entity does not have an existing agreement to pay embedded system costs], a load serving entity with load that sinks outside the transmission organization's region is entitled to receive long-term firm transmission rights from existing system capacity to support that load to the extent that capacity is available after the needs of the load serving entities whose loads are within the region have been met.[43]

In LIPA's view, the allocation preference expressed in paragraph 80 only applies with respect to the initial allocation of long-term firm transmission rights to an external load serving entity that has no existing agreement with the ISO/RTO or does not hold long-term rights for which such ISO/RTO plans and constructs its transmission system.

25. LIPA argues specifically that firm transmission withdrawal rights in PJM meet the standard articulated by the Commission in paragraph 78 of Order No. 681–A and, according to LIPA, these withdrawal rights should entitle external load serving entities to the same rights as internal load serving entities. As LIPA explains, PJM awards firm transmission withdrawal rights for merchant transmission lines that include the right to withdraw energy and capacity from the PJM system up to a specific megawatt level. LIPA explains that PJM first subjects the award of such firm transmission withdrawal rights to system impact studies through the interconnection process and considers any potential system upgrades. Next, according to LIPA, PJM includes such

[36] *See Cal. Indep. Sys. Operator Corp.*, 120 FERC ¶ 61,023, at P 188 (2007), *reh'g denied*, 124 FERC ¶ 61,095, at P 42–45 (2008) (accepting MRTU Tariff section 36.9, which establishes an external load serving entity's eligibility for firm transmission rights based on a forward-looking showing of need).

[37] SMUD Rehearing Request at 14. ''ISO'' refers to ''Independent System Operator'' and ''RTO'' refers to ''Regional Transmission Operator.''

[38] *Id.*

[39] *Id.* at 14–15.

[40] *Id.*

[41] *See MRTU Rehearing Order*, 119 FERC ¶ 61,076 at P 373 (rejecting request to give external load serving entities the opportunity to demonstrate reliance on the CAISO grid in order to avoid prepaying for the transmission service necessary to qualify for allocation of congestion revenue rights, which can be converted into long-term firm transmission rights).

[42] We note that the DC Circuit Court upheld the Commission's finding that PG&E's notice of termination of its long-term contract with SMUD was just and reasonable. *Sacramento Municipal District* v. *FERC*, 474 F.3d 797, 801 (DC Cir. 2007). Nevertheless, the CAISO allows an external load serving entity such as SMUD to obtain long-term firm transmission rights through a combination of pre-payment of wheeling access charges and ownership of or contract for generation within the CAISO. *See generally* MRTU Tariff § 36.9. In addition, the MRTU Tariff allows SMUD to rollover a short-term firm transmission right indefinitely and use this to hedge CAISO congestion charges, as long as this does not interfere with the simultaneous feasibility of other allocated rights. *Id.* § 36.9.5.

[43] Order No. 681–A, 117 FERC ¶ 61,201 at P 80.

firm transmission withdrawal rights in its Regional Transmission Enhancement Plan (RTEP) and thereby plans for and constructs its system to ensure the availability of such firm transmission withdrawal rights. LIPA further states that PJM has proposed (and the Commission has agreed) that the costs of RTEP upgrades to support such withdrawal rights may be allocated to merchant transmission lines. LIPA adds that the use of withdrawal rights also requires scheduling of transmission service over the PJM system, for which the customer also then pays a ''Border Rate'' charged to exports from the system, and through which PJM recovers the embedded system costs. LIPA asks the Commission to clarify that the lower allocation priority and potential for reduced allocation of long-term firm transmission rights discussed in paragraph 80 does not apply to holders of long-term firm transmission rights such as firm withdrawal rights. Further, LIPA argues that any reduction contemplated under paragraph 80 should only be triggered when, as part of the evaluation of all internal and external load serving entity requests, there is a binding constraint that does not allow a full allocation of long-term firm transmission rights to qualifying load serving entities. LIPA states that, in such a case, the initial request for long-term firm transmission rights may be prorated downward to ensure that an internal load serving entity or external load serving entity with an existing agreement or long-term rights receives its full allocation of long-term firm transmission rights.

Commission Determination

26. We grant in part and deny in part LIPA's requested clarification. First, we clarify that an external load serving entity may receive the same allocation priority as an internal load serving entity if the external load serving entity can demonstrate that the transmission organization plans and constructs its transmission system to support the external load serving entity's load serving requirements and the external load serving entity contributes to the costs incurred for such purpose. We further clarify that paragraph 80 of Order No. 681–A is intended to apply only to situations where a load serving entity with load external to the region makes an initial request to obtain long-term firm transmission rights. That is, paragraph 80 serves only to establish the initial priority for the allocation of long-term firm transmission rights to an external load serving entity that has not historically contributed to the embedded costs of the transmission system, and for whom the transmission organization has not planned and constructed its transmission system.[44]

27. LIPA also requests clarification of the conditions under which a reduced allocation of long-term firm transmission rights is contemplated under paragraph 80. We clarify that an external load serving entity may be allocated fewer long-term firm transmission rights than it requests in a situation where its initial request for long-term firm transmission rights cannot be accommodated by the system capacity that is available after the needs of the load serving entities whose loads are within the region have been met. This rule would apply to an initial request where the transmission organization has not historically planned and constructed its system to meet the external load serving entity's load serving needs.

28. However, we decline to grant LIPA's requested clarification that its firm transmission withdrawal rights in PJM meet the standard articulated by the Commission in paragraph 78 of Order No. 681–A, such that these rights should entitle external load serving entities like LIPA to be granted the same rights as internal load serving entities. Whether these firm withdrawal rights qualify LIPA for receipt of long-term firm transmission rights in PJM requires a fact-based determination that is outside the scope of a general rulemaking proceeding.[45]

4. Comparable Treatment for External and Internal Load Serving Entities

29. LIPA asks the Commission to clarify that ''qualifying'' external load serving entities are able to participate in the same phase of long-term firm transmission rights allocation as internal load serving entities and receive a long-term firm transmission right of the same length and attributes as an internal load serving entity.[46] LIPA states that, as noted in Order No. 681–A, Order No. 681 provides that transmission organizations must make long-term firm transmission rights available to load serving entities with term lengths and/or renewal rights that are sufficient to meet load serving entities' need to hedge long-term power supply arrangements. LIPA points out that the Commission required long-term firm transmission rights to have a specific term length and/or use of renewal rights to provide firm coverage for at least a 10-year period.[47] LIPA states that a 10-year term length, renewal rights, and firmness of coverage are the ''backbone'' of long-term firm transmission rights, which LIPA argues should not differ regardless whether a load serving entity is internal or external to the ISO or RTO.

30. Also focusing on this issue, SMUD challenges the Commission's ruling that only load serving entities in a transmission organization's control area or those load serving entities with existing long-term firm service contracts would qualify for a first-tier allocation[48] of long-term firm service rights. SMUD argues that this ruling prejudices those load serving entities located outside the CAISO's control area whose long-term firm service agreements lapsed, with no long-term firm service replacement, due to the CAISO's ''history of procrastination'' in developing such rights.

31. Furthermore, SMUD asserts that the Commission failed to engage in reasoned decision-making by inconsistently applying its precedent and suggesting that a transmission organization may give preference to load serving entities located in its own control area over those located outside its control area. SMUD states that the Commission offered no valid grounds for its departure from Order No. 888,

[44] *See Midwest Indep. Transmission Sys. Operator, Inc.,* 121 FERC ¶ 61,062, at P 40–41 (2007), *order on reh'g,* 123 FERC ¶ 61,178 (2008), and *Midwest Indep. Transmission Sys. Operator, Inc.,* 121 FERC ¶ 61,063, at P 53–54 (2007) (finding that stage 2 eligibility for long-term firm transmission rights to cover transmission service obtained after the reference year is not unduly discriminatory).

[45] Indeed, it appears this issue has been appropriately asked and answered in the compliance phase of this rulemaking proceeding. *See PJM Interconnection, L.L.C.,* 119 FERC ¶ 61,144 at P 37–44, *clarified on other grounds,* 121 FERC ¶ 61,073 (denying LIPA's request for preferential allocation of long-term firm transmission rights in PJM because LIPA did not take service from PJM during the historical reference year, nor does it continue to pay the embedded cost of the PJM transmission system). The Commission notes, however, that on Jan. 28, 2009, in Docket No. ER09–585–000, PJM filed tariff revisions that would allow external load-serving entities, including holders of firm withdrawal rights, to obtain long-term firm transmission rights, provided certain conditions are met.

[46] LIPA states that, for purposes of its clarification request, qualifying external load serving entities are those entities for which the transmission organization plans and constructs its transmission system to support the load serving entity's load and the load serving entity contributes to the cost that the transmission organization incurs for that purpose. LIPA Rehearing Request at 3 & n.9.

[47] *Id.* at 4 & n.10.

[48] SMUD refers to the fact that the CAISO, like other ISOs/RTOs, uses nomination tiers to allocate long-term firm transmission rights. In each tier, a load serving entity is allowed to nominate a percentage of the total amount of transmission rights it is eligible to request. The ISO/RTO then runs a simultaneous feasibility test on all nominated rights to determine the feasible set of rights that it can award. Load serving entities typically nominate their most highly-valued rights in the first tier. *See generally Cal. Indep. Sys. Operator Corp.,* 125 FERC ¶ 61,153 (2008).

and cases interpreting Order No. 888, which SMUD argues require transmission providers to offer service to all customers on a non-discriminatory basis.[49] In addition, SMUD argues that the Commission's proposal to distinguish among load serving entities on the basis of control area is inconsistent with section 217 of the FPA. Specifically, SMUD asserts that allowing transmission organizations to impose a prepayment obligation [50] on external load serving entities is unduly discriminatory.

32. First, SMUD argues that the principle that a transmission provider may place preconditions on a customer's right to service based on whether it is located inside or outside of the transmission provider's control area ''turns Order No. 888 on its head.'' [51] Citing the NOPR for Order No. 890,[52] SMUD asserts that the Commission has made clear that transmission organizations covered by Order No. 681 must continue to offer service as good as or superior to that offered under an Order No. 888 Open Access Transmission Tariff (OATT). SMUD states that under Order No. 888, a transmission provider is required to provide customers non-discriminatory access to the grid equivalent to the transmission service it provides itself.[53] SMUD posits that if a transmission owner with a traditional OATT were to treat a customer outside its control area differently than it treats its own control area load, that transmission owner would be engaging in blatantly discriminatory conduct. SMUD insists that the Commission's interpretation of *New England Power Pool* leads to the conclusion that transmission owners with OATTs could turn control of their facilities over to an ISO and then have the ISO discriminate against those same customers, customers still dependent on their transmission, but now located outside the ISO's control area.

33. Next, SMUD argues that the Commission's interpretation of *New England Power Pool* is an ''unexplained departure'' from its holding in *Mid-Continent Area Power Pool,* 87 FERC ¶ 61,075 (1999) (*MAPP*). SMUD quotes *MAPP:*

> Order No. 888 requires that pool compliance tariffs provide service to members and non-members alike. We stated that members of a loose power pool, as well as non-members, must have access to the same transmission services within that power pool on a comparable basis and pay the same or a comparable rate for those services.[54]

SMUD argues that, just as transmission providers within a power pool cannot condition access to transmission service on a customer's willingness to join the pool, it is unduly discriminatory to condition a transmission customer's access to firm transmission service on its location within a transmission provider's control area.

34. Third, SMUD argues that, far from supporting the notion that customers outside the control area should be treated differently, *New England Power Pool* reaffirms the principle that customers outside an ISO's control area that are committed to contributing to the ISO's fixed costs under a long-term firm transmission agreement must be treated on a non-discriminatory basis and that they should not be given lower priority based on their location outside the transmission provider's control area.

Commission Determination

35. In response to the requests of LIPA and SMUD, we clarify that the transmission organization's criteria for determining a load serving entity's eligibility to receive a preference in the allocation of long-term firm transmission rights must not be unduly discriminatory as between internal and external load serving entities. That is, the transmission organization may apply a variety of eligibility criteria that are appropriate for its region, as long as it applies those criteria in a manner that is not unduly discriminatory.[55] For example, to be eligible for an allocation preference, the transmission organization may require a load serving entity to demonstrate that it has a long-term power supply arrangement from a historical point of receipt to a historical point of delivery, and that it will continue to contribute to the embedded cost of the transmission system for the duration of the period for which the load serving entity intends to hold the long-term firm transmission right. Such criteria would not be unduly discriminatory if they are tailored to meet the transmission organization's legitimate need to verify entitlement to allocation of the long-term rights, *i.e.*, that the external load serving entity intends to use these rights to serve its customers. If the transmission organization allocates long-term firm transmission rights using a system of stages or tiers, we would expect all qualified load serving entities to be placed in the same allocation stage or tier without regard to whether its load is internal or external to the region.

36. In response to the assertion by SMUD that the Commission's interpretation of *New England Power Pool* is an unexplained departure from precedent, we clarify that the citation to *New England Power Pool* in footnote 74 of Order No. 681–A was the result of an inadvertent drafting error. Nevertheless, we reiterate our determination that it is not unduly discriminatory for a transmission organization to impose reasonable, additional requirements on customers external to the transmission organization's control area as a precondition to receiving long-term firm transmission rights.[56] It is within the transmission organization's purview to create rules that aim to ensure equitable allocation/distribution of these potentially valuable rights.

37. However, in response to LIPA, we clarify that any differences in the attributes (*e.g.*, length, renewal rights

[49] SMUD Rehearing Request at 6–7 (referencing *Promoting Wholesale Competition Through Open Access Non-Discriminatory Transmission Services by Public Utilities; Recovery of Stranded Costs by Public Utilities and Transmitting Utilities,* Order No. 888, FERC Stats. & Regs. ¶ 31,036 (1996), *order on reh'g,* Order No. 888–A, FERC Stats. & Regs. ¶ 31,048, *order on reh'g,* Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g,* Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group* v. *FERC,* 225 F.3d 667 (D.C. Cir. 2000), *aff'd sub nom. New York* v. *FERC,* 535 U.S. 1 (2002)).

[50] By ''prepayment obligation,'' SMUD refers to the fact that the CAISO, for example, requires an external load serving entity to agree in advance to pay a year's worth of wheeling access charges to be eligible for allocation of long-term firm transmission rights on the same basis as internal load serving entities. *See MRTU Order,* 116 FERC ¶ 61,274 at P 706–15; *MRTU Rehearing Order,* 119 FERC ¶ 61,076 at P 358 (discussing prepayment in connection with short-term firm transmission rights, which may be converted to long-term rights); *Cal. Indep. Sys. Operator Corp.,* 120 FERC ¶ 61,023 at P 266.

[51] SMUD Rehearing Request at 6.

[52] *Id.* (citing *Preventing Undue Discrimination and Preference in Transmission Service,* Notice of Proposed Rulemaking, Docket Nos. RM05–17–000 and RM05–25–000, FERC Stats. & Regs. ¶ 32,603, at P 100 (2006), *order issuing final rule* Order No. 890, FERC Stats. & Regs. ¶ 31,241 (2007), *order on reh'g,* Order No. 890-A, 73 FR 2984 (Jan. 16, 2008), FERC Stats. & Regs. ¶ 31,261 (2007), *order on reh'g,* Order No. 890–B, 73 FR 39,092 (July 8, 2008), 123 FERC ¶ 61,299 (2008)).

[53] *Id.* (citing Order No. 888, FERC Stats. & Regs. ¶ 31,036 at 31,760).

[54] SMUD Rehearing Request at 7 (citing *MAPP,* 87 FERC ¶ 61,075 at 61,309–10).

[55] *See Regional Transmission Organizations,* Order No. 2000–A, 65 FR 12,088 (2000), FERC Stats. & Regs. ¶ 31,092 at 31,385 (2000) (''We do not agree with the premise of some of the petitioners who conclude that rate differences of any type [between RTO participants and non-participants] would constitute undue discrimination.''), *aff'd sub nom., Public Util. Dist. No. 1 of Snohomish, Wash.* v. *FERC,* 272 F.3d 607 (DC Cir. 2001).

[56] *See MRTU Order,* 116 FERC ¶ 61,274 at P 766 (stating that external load and internal load are not similarly situated with respect to their reliance on the transmission organization's grid); *MRTU Rehearing Order,* 119 FERC ¶ 61,076, at P 377 (2007) (requiring external load serving entities to satisfy additional requirements to verify need for long-term firm transmission rights does not violate Order No. 888 because external load serving entities are not denied transmission service and all customers receive the same service under the MRTU Tariff).

and firmness of coverage) of long-term firm transmission rights that are allocated among load serving entities should not be based on whether a load serving entity is internal or external to the transmission organization.

5. Marginal Losses

38. In Order No. 681, we concluded that section 217(b)(4) does not address marginal loss charges.[57] Noting that each transmission organization that operates an organized electricity market has established methods for refunding marginal loss surpluses that reflect regional preferences, which the Commission has approved, we decided not to overturn those decisions in this proceeding.[58] In Order No. 681–A, we upheld our statutory interpretation that section 217(b)(4) of the FPA does not address marginal loss charges.[59] First, we explained that the issue of hedging long-term marginal loss charges is distinct from the issue of hedging marginal congestion charges. Congestion charges, we said, arise in part due to transmission constraints, and transmission organizations allocate transmission rights to hedge these costs. Marginal loss charges, we noted, are similar to congestion costs because they are a function of locational energy prices and line loadings. However, significantly, ''the development of a financial instrument or other means for hedging of marginal losses has not been accomplished to date in any of the organized electricity markets.'' [60]

39. Next, we parsed the language of the statute and explained that the terms used in section 217(b)(4)—''firm transmission rights'' and ''equivalent tradable or financial rights''—''are consistent with terminology traditionally used to discuss hedging of congestion, rather than marginal losses.'' [61] We further explained that, since we do not interpret EPAct 2005 as requiring transmission organizations to provide long-term firm transmission rights with properties that are fundamentally different from those of the short-term rights that they now offer, we do not interpret the statute as requiring hedging of marginal losses. We emphasized that our interpretation of EPAct 2005 as not *requiring* hedging of marginal losses does not preclude future market design changes that *allow* hedging of losses.[62] Significantly, we encouraged transmission organizations to explore methods to assist load serving entities and others to obtain a hedge for marginal losses.[63]

40. On rehearing, SMUD argues that, in light of FPA requirements and Congress' clear intent that ''financially firm'' transmission service would provide customers the equivalent of firm physical rights, financial rights must include a hedge against marginal losses. SMUD argues that the Commission contravened Order No. 888 and the plain language of the FPA by concluding that long-term firm transmission rights need only be similar to the short-term transmission rights now being offered by most transmission organizations, and that long-term firm transmission rights need not include a hedge against marginal losses because short-term rights do not include such a hedge. SMUD argues that the Commission's conclusion that long-term rights should be similar to short-term rights with respect to their lack of a hedge against marginal losses has no record, logical, or factual basis.

41. According to SMUD, the purpose of section 217(b)(4) of the FPA, reflected in the language of the statute, is to require transmission organizations to provide long-term firm service based on financial rights that is equivalent to long-term service based on ''firm,'' *i.e.*, ''physical'' transmission rights. SMUD argues that, since, as a matter of historical practice, long-term physical rights do not expose customers to marginal losses, then neither should their financial rights counterparts.

42. SMUD reiterates its initial comments in this proceeding, asserting that marginal losses pose at least as big an uncertainty as congestion charges and, without hedges to insulate parties from the risks marginal loss exposure creates, interregional trade will be constrained. SMUD suggests that the Commission's position is unsupported because most transmission organizations did not include marginal losses when they started their organized markets, and PJM only recently began offering them, so the past cannot be a valid prologue for the future. SMUD argues that relying on the possibility that transmission organizations may voluntarily offer hedges for marginal loss exposure is insufficient to ensure equivalence between financial and physical rights-based firm service. SMUD states that on rehearing the Commission should require transmission organizations to either: (1) Offer long-term firm service customers a hedge against marginal losses; or (2) exempt long-term firm customers from those charges and charge actual or estimated system average losses.

Commission Determination

43. We deny SMUD's request for rehearing concerning marginal losses, primarily for the reasons discussed in Order Nos. 681 and 681–A.[64] First, as we explained in Order No. 681–A, the issue of hedging long-term marginal loss charges is distinct from the issue of hedging long-term marginal congestion charges, and the language of section 217 of the FPA is silent regarding marginal losses.[65]

44. We disagree with SMUD's argument that the language of the statute mandates a hedge against marginal losses for long-term firm service customers. SMUD argues that the term ''firm service'' in the statute denotes physical transmission service, and long-term physical rights do not expose customers to marginal losses, so neither should their financial counterparts.[66] However, SMUD ignores the fact that transmission losses and congestion are distinct features of transmission service. While physical rights customers may not have been exposed to marginal losses, they generally had contractual arrangements concerning responsibility for losses on the transmission system.

45. We further object to SMUD's assertion that, in Order No. 681–A, the Commission declared, without record, logical or factual basis, that long-term firm transmission rights should have the same characteristics as short-term rights. Rather, the Commission simply observed that it did not interpret EPAct 2005 as requiring transmission organizations to provide long-term firm transmission rights that are fundamentally different from the short-term rights they now offer.[67] Specifically, transmission organizations with short-term rights do not provide hedges for marginal losses, and EPAct 2005 does not expressly require a hedge for marginal losses.

46. Hedging marginal losses is more complex than hedging congestion costs due to the variable nature of losses. While it is theoretically possible to design a different type of firm transmission right—an unbalanced firm transmission right—to hedge against both congestion and marginal losses, such designs are only in the experimental stage. No transmission

[57] Order No. 681, FERC Stats. & Regs. ¶ 31,226 at P 478.

[58] *Id.*

[59] Order No. 681–A, 117 FERC ¶ 61,201 at P 105–06.

[60] *Id.* P 105.

[61] *Id.* P 106.

[62] *Id.*

[63] *Id.*

[64] Order No. 681, FERC Stats. & Regs. ¶ 31,226 at P 478; Order No. 681–A, 117 FERC ¶ 61,201 at P 105–06.

[65] Order No. 681–A, 117 FERC ¶ 61,201 at P 105–06.

[66] SMUD Rehearing Request at 12.

[67] Order No. 681–A, 117 FERC ¶ 61,201 at P 106.

organization has yet to implement a hedge for marginal losses. Accordingly, we decline to order hedging of marginal losses at this time. Nevertheless, we recognize that a marginal loss hedge could provide benefits to certain market participants. The Commission supports development of a marginal loss hedging product if its design progresses beyond the theoretical level and it can be developed cost-effectively.

47. The Commission also denies SMUD's request to exempt long-term firm transmission customers from marginal losses and charge them actual or estimated system average losses. This raises a market design issue that has implications beyond the design of long-term firm transmission rights and is more appropriately resolved by each transmission organization on a case-by-case basis. Moreover, since we find that EPAct 2005 does not address marginal losses, this request is beyond the scope of this rulemaking proceeding.

By the Commission.

Kimberly D. Bose,

Secretary.

[FR Doc. E9–6698 Filed 3–25–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1, 26, 201, 203, 206, 310, 312, 314, 320, and 600

[Docket No. FDA–2009–N–0133]

Change of Addresses and Names; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect a change of address for the Center for Drug Evaluation and Research's (CDER's) Central Document Room in Beltsville, MD; the relocation of certain CDER offices to the White Oak campus in Silver Spring, MD; and changes of the names of certain CDER organizational units. This action is editorial in nature and is intended to ensure the accuracy and clarity of the agency's regulations.

DATES: This rule is effective March 26, 2009.

FOR FURTHER INFORMATION CONTACT: Wendy Aaronson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 1128, Silver Spring, MD 20993–0002, 301–796–0410.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in parts 1, 26, 201, 203, 206, 310, 312, 314, 320, and 600 (21 CFR parts 1, 26, 201, 203, 206, 310, 312, 314, 320, and 600) to reflect the following changes: (1) Names of certain CDER organizational units; (2) a change of address for CDER's Central Document Room in Beltsville, MD; and (3) the relocation of certain CDER offices to the White Oak campus in Silver Spring, MD. The addresses are locations to which applicants must submit information related to marketing applications or products regulated by CDER or from which the public can request information. Where appropriate, Internet addresses for obtaining information and forms are added and outdated addresses are removed.

The technical amendments made by this document are largely related to paper submissions; however, FDA is committed to adapting its business practices to evolving technology, including using the significant advancements in Web-based, electronic systems. We anticipate that, in future rulemakings, Web-based filing of most submissions will eventually be required. We anticipate that when a change to an electronic submission system is implemented, we will provide guidance to address any technical questions related to such submissions.

The technical amendments, reflected in the regulatory text of this final rule, are as follows:

- In § 1.101(d)(2)(ii), the address to submit notifications for products regulated by CDER exported under section 802 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 382) is changed to the White Oak campus.
- In Appendix E to subpart A of part 26, the contact information for CDER's Office of Compliance is updated to the White Oak campus.
- In § 201.58, the address to submit requests for waivers of labeling requirements is updated to the Beltsville Central Document Room.
- In § 203.12, the CDER address for notification of an appeal from an adverse decision regarding reimportation of an insulin-containing or prescription drug by a district office is changed to the White Oak campus.
- In § 203.37(e), the address to submit information regarding falsification of drug sample records or loss or theft of samples for prescription drugs and biological products regulated by CDER is changed to the White Oak campus.
- In § 203.70(b)(1), the address to apply for a reward for providing information leading to a criminal proceeding or conviction related to the sale, purchase, or trade of a drug sample is changed to the White Oak campus.
- In § 206.7(b)(1)(i), the address to request exemptions from imprinting requirements for solid oral dosage form drugs is updated to the Beltsville Central Document Room.
- In § 310.6(e), the address for interested parties to submit the names of drug products, and of their manufacturers or distributors, that should be subject to the same purchasing and regulatory policies as those reviewed by the Drug Efficacy Study Group is changed to the White Oak campus.
- In §§ 310.305(c) and 314.98(b), the address to submit postmarketing safety reports is updated to the Beltsville Central Document Room. (Note that applicants and any person other than the applicant whose name appears on the label of an approved drug product as a manufacturer, packer, or distributor may also elect to submit postmarketing safety reports in electronic format.)
- In §§ 310.305(d)(4) and 314.80(f)(4), the address to obtain reporting forms is updated to reflect Internet availability.
- In §§ 310.501(e) and 310.515(d), the name and address to request labeling guidance for estrogen drug products are updated to the Division of Reproductive and Urologic Products and the White Oak campus.
- In § 312.140(b), mailing instructions are updated to ensure submissions are addressed properly.
- In §§ 312.145(b) and 314.445(b), the CDER unit from which to request a list of CDER guidances is updated to the Division of Drug Information. The address is updated to the White Oak campus, and an Internet address is added to reflect the availability of the list on the Internet.
- In § 314.80(d)(2) and (f)(3)(ii), the CDER unit to contact regarding alternative reporting formats is updated to the Office of Surveillance and Epidemiology.
- In § 314.81(b)(3)(i), the address to obtain Form FDA–2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) is updated to reflect Internet availability.
- In § 314.200(a)(3), the address to request opinions of the applicability of a notice of opportunity for a hearing published in the **Federal Register** to a specific product that may be identical, related, or similar to a product listed in the notice is changed to the White Oak campus.
- In § 314.440(a), an outdated address to submit applications, abbreviated applications, and related