interest on any delinquent APHIS user fee; or

(iv) Payment has been dishonored;

(2) APHIS will estimate the user fee to be paid; any difference between the estimate and the actual amount owed to APHIS will be resolved as soon as reasonably possible following the delivery of the service, with APHIS returning any excess to the payor or billing the payor for the amount due;

(3) The prepayment must be in guaranteed form, such as money order, certified check, or cash. Prepayment in guaranteed form will continue until the debtor pays the delinquent debt;

(4) Cash payments will be accepted only at a location designated by the APHIS employee during normal business hours; and

(5) Service will be denied until the debt is paid if:

(i) For unbilled fees, the user fee is unpaid 90 days after the date the pertinent regulatory provision indicates payment is due;

(ii) For billed fees, the user fee is unpaid 90 days after date of bill;

(iii) The person requesting the service has not paid the late payment penalty or interest on any delinquent APHIS user fee; or

(iv) Payment has been dishonored.

(b) * * *

(3) If a user fee is due for a test conducted by APHIS, APHIS will not release the test result or any endorsed certificate; and

(4) If a user fee is due for a diagnostic reagent, slide set, tissue set, or sterilization by gamma radiation, APHIS will not release the diagnostic reagent, slide set, tissue set, or sterilized material.

(c) If for unbilled user fees, the user fees are unpaid 30 days after that date the pertinent regulatory provisions indicates payment is due, or if billed, are unpaid 30 days after the date of the bill, APHIS will impose a late payment penalty and interest charges in accordance with 31 U.S.C. 3717.

* * * * *

Done in Washington, DC, this 15th day of July 1993.

Eugene Branstool,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–17300 Filed 7–20–93; 8:45 am]

BILLING CODE 3410–34–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Requirements for Child-Resistant Packaging; Products Containing Loperamide

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: Under the Poison Prevention Packaging Act of 1970, the Commission issues a rule requiring child-resistant packaging for products containing more than 0.045 milligrams (mg) of loperamide in a single package. These requirements are issued because the Commission has determined that child-resistant packaging is required to protect children under 5 years of age from serious personal injury and serious illness resulting from ingesting loperamide. Loperamide is used as an antidiarrheal medication that is marketed in both prescription and over-the-counter forms.

EFFECTIVE DATE: The rule is effective on August 20, 1993.

FOR FURTHER INFORMATION CONTACT: Michael T. Bogumill, Division of Regulatory Management, Office of Compliance and Enforcement, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504-0400.

SUPPLEMENTARY INFORMATION:

A. Background

1. Relevant Statutes and Regulations

The Poison Prevention Packaging Act of 1970 (the "PPPA"), 15 U.S.C. 1471-1476, authorizes the Commission to establish standards for the "special packaging" of any household substance if (1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance and (2) the special packaging is technically feasible, practicable, and appropriate for such substance. Special packaging, also referred to as "child-resistant packaging," is defined as packaging that is (1) designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and (2) not difficult for normal adults to use properly. (It does not mean, however, packaging which all such children cannot open, or obtain a toxic or harmful amount from, within a reasonable time.) Under the PPPA, effectiveness standards have been established for special packaging (16 CFR 1700.15), as has a procedure for evaluating the effectiveness (§ 1700.20). Regulations have been issued requiring special packaging for a number of household products (§ 1700.14). The findings that the Commission must make in order to issue a standard requiring child-resistant ("CR") packaging for a product are discussed below in Section D of this notice. For the purposes of the PPPA, the amount of a substance "in a single package" that triggers the requirement to place the product in CR packaging refers to the total amount in a single retail unit of the substance.

One of the categories of products for which CR packaging is required is prescription drugs intended for oral administration to humans, with specified exemptions. 16 CFR 1700.14(a)(10). When the FDA releases a drug from prescription requirements and the drug can then be bought over-the-counter ("OTC"), the drug is no longer subject to the child resistant packaging requirements for prescription drugs.

Where prescription drugs are subject to a special packaging standard, section 4(b) of the PPPA allows such products to be sold in non-CR packaging only when (1) directed by the prescribing medical practitioner or (2) requested by the purchaser. 15 U.S.C. 1473(b).

For nonprescription (over-the-counter, or "OTC") products subject to special packaging standards, section 4(a) of the PPPA allows the manufacturer or packer to package the product in non-CR packaging only if (1) the manufacturer (or packer) also supplies the substance in CR packages and (2) the non-CR packages bear conspicuous labeling stating: "This package for households without young children." 15 U.S.C. 1473(a). If the package is too small to accommodate this label statement, the package may bear a label stating: "Package not child-resistant." 16 CFR 1700.5(b). The right of the manufacturer or packer to market a single size of the product in noncomplying packaging under these conditions is termed the "single-size exemption."

The Commission may restrict the right to market a single size in noncomplying packaging if the Commission finds that the substance is not also being supplied in popular size packages that comply with the standard. 15 U.S.C. 1473(c). In this case, the Commission may, after giving the manufacturer or packer an

opportunity to comply with the purposes of the PPPA and an opportunity for a hearing, order that the substance be packaged exclusively in CR packaging. To issue such an order, the Commission must find that the exclusive use of special packaging is necessary to accomplish the purposes of the PPPA.

2. Loperamide

Loperamide is an antidiarrheal medication that was first marketed by its patent holder in 1976 as a prescription drug. A capsule preparation of loperamide is available only by prescription and, since this is an oral prescription drug for humans, is required to be in CR packaging. In 1988, however, the Food and Drug Administration granted OTC status to a caplet (formulation ingredients compressed into the shape of a capsule) containing the same amount of loperamide as the prescription product and to a liquid preparation. These forms of the drug are marketed OTC in CR packaging by the original manufacturer.

The patent for loperamide expired in January of 1990, and other manufacturers may now apply to FDA for approval to make and market loperamide. Additional suppliers have approval to market liquid and solid OTC preparations, containing the same amount of loperamide as the original manufacturer's product.

Loperamide is structurally related to the opium alkaloids and acts by slowing intestinal motility and by reducing stomach and intestinal secretions. Loperamide is not recommended for children less than 2 years of age, as these children appear to be more sensitive to the drug's central nervous system (CNS) effects than are adults. The drug should not be used for any age group if diarrhea is accompanied by fever greater than 101°F or when blood appears in the stool. To prevent toxic accumulation of the drug, loperamide should be used with caution in individuals with liver disorders. Loperamide should not be used for more than 2 days, unless directed by a physician.

The maximum daily nonprescription dosage of loperamide is 8 milligrams (mg) for adults, 6 mg for children 9 to 11 years of age, 4 mg for children 6 to 8 years of age, and 3 mg for children 2 to 5 years of age. Currently, liquid OTC loperamide contains 1 mg of loperamide per 5 milliliters (ml) of liquid and the OTC caplet form contains 2 mg of loperamide per caplet. The original OTC loperamide products on the market are in CR packaging, as are other products that have come on the market. (Ref. No. 1.)

After considering the toxicity of loperamide and its availability in the home, the Commission proposed a rule under the PPPA to require special packaging for products containing more than 0.045 mg of loperamide in a single package. 57 FR 47020 (Oct. 14, 1992). The notice of proposed rulemaking provided a 75 day comment period. The Commission received only one comment which came from the American Society of Hospital Pharmacists ("ASHP") and supported the proposed rule. ASHP's letter stated that ASHP believed that products containing more than 0.045 milligrams of loperamide in a single package are hazardous to children and should be in child-resistant packaging. (Ref. No. 5.)

B. Toxicity

Animal and human pharmacological and toxicological data show that overdosage of loperamide can cause stomach and intestinal irritation (nausea, vomiting, abdominal pain, and constipation), abdominal distention and obstruction of the bowel, CNS effects (drowsiness, dizziness, muscular spasms, and convulsions), respiratory depression (periodic cessation of breathing, cyanosis, and coma), and death. In case of overdosage, activated charcoal and washing out the stomach are recommended. The patient should be frequently monitored for CNS and respiratory depression because of the prolonged action of loperamide. If signs of CNS or respiratory depression are present, naloxone, a drug which reverses the depressant effects of narcotics, should be administered.

The majority of the incidents of loperamide toxicity reported in the scientific literature occurred in foreign countries and involved the intentional administration of loperamide to children. The symptoms of overdosage ranged from nausea and dizziness to severe and life-threatening effects, including respiratory depression, coma, convulsions, and bowel obstruction and perforation. There are 11 deaths of children under age 5 reported.[1] The smallest dose reported (measured as mg of loperamide per kilogram (kg) of body weight) that resulted in adverse symptoms was 0.045 mg/kg; this (single oral) dose caused bowel obstruction with stool retention for 7 days in a 1-year-old child. (Ref. No. 1.)

The CPSC Children and Poisoning ("CAP") database for 1978 through April 1993 shows 12 ingestions of loperamide by children under 5 years of age treated in hospital emergency rooms participating in the National Electronic Injury Surveillance System ("NEISS"). Four of the children were admitted to the hospital. (Ref. No. 7.)

The American Association of Poison Control Centers' National Data Collection System ("AAPCC") includes cases of exposure reported by participating poison control centers. For 1990, 505 accidental ingestions of loperamide by children under 5 years of age were reported. Of these, 198 were seen by physicians and 75 experienced mild effects (symptoms resolved without treatment) to moderate effects (some medical treatment required). No life-threatening effects or fatalities were attributed to loperamide from this database. (Ref. Nos. 1 & 7.)

C. Level for Regulation

For incidents where the amount of loperamide ingested was known, severe adverse respiratory effects (periodic cessation of breathing, cyanosis, and coma), CNS effects (drowsiness, muscular spasms, and convulsions), and/or gastrointestinal disturbances (abdominal distention, bowel obstruction, and intestinal perforation) were reported following administration of from 0.045 to 2.0 mg/kg of loperamide (with most incidents involving ingestions of between 0.26 and 1.0 mg/kg). In one case, death occurred following a dose of 1.0 mg/kg of loperamide. Insufficient information was available to determine the doses of loperamide involved with the other 10 deaths reported in the medical literature.

Serious illness has been reported after ingestion of 0.045 mg/kg. There is no information about the amount of loperamide that would not cause serious illness, serious injury, or death in infants or children under 2 years of age. Without such data, the Commission's staff recommends that the lowest level known to have caused serious illness in humans (0.045 mg/kg) be reduced by a factor of 10 (referred to as an "uncertainty factor") to take into account biological variability. When this is done for a 10-kg (22.2 lb) child, the staff concludes that loperamide preparations containing more than 0.045 mg of loperamide in a single container should be subject to CR packaging requirements. This amount is contained in one-twentieth of a teaspoon of liquid loperamide or in one-fourtieth of a caplet of loperamide. (Ref. No. 1.)

[1] Seven deaths occurred in the hospital. In four cases the children were seriously ill and the parents requested permission to take them home before they died.

D. Statutory Considerations

1. Hazard to Children

Although the reported cases of death and life-threatening effects involved intentional administration of loperamide, the toxicity data from these incidents show that the amounts of loperamide available in OTC preparations is sufficient to cause serious illness and serious injury in children. Even though the OTC loperamide preparations currently on the market are voluntarily sold in CR packaging, the Commission concludes that a regulation is needed to ensure that those that are now in child resistant packaging and future products containing loperamide, including products from additional manufacturers that could be introduced now that loperamide's patent has expired, will be subject to CR requirements.

Pursuant to section 3(a) of the PPPA, 15 U.S.C. 1472(a), the Commission finds that because of the toxic nature of loperamide preparations, described above, and the accessibility of such preparations to children in the home, the degree and nature of the hazard to children in the availability of such substances, by reason of their packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances.

2. Technical Feasibility, Practicability, and Appropriateness

In issuing a standard for special packaging under the PPPA, the Commission is required by section 3(a)(2) of the PPPA, 15 U.S.C. 1472(a)(2), to find that the special packaging is "technically feasible, practicable, and appropriate." Technical feasibility exists when technology exists or readily can be developed and implemented by the effective date to produce packaging conforming to the standards. Practicability means that special packaging complying with the standards can utilize modern mass production and assembly line techniques. Appropriateness exists when packaging complying with the standards will adequately protect the integrity of the substance and not interfere with the intended storage or use. Because the currently-marketed forms of loperamide are in CR packaging, the Commission concludes that special packaging for loperamide preparations is technically feasible, practicable, and appropriate.

3. Reasonableness

In establishing a special packaging standard, section 3(b) of the PPPA requires the Commission to consider the available data concerning whether the standard is reasonable. 15 U.S.C. 1472(b).

After considering the available data, the Commission concludes that there are no data that warrant a conclusion that the rule is not reasonable.

4. Other Considerations

Section 3(b) of the PPPA also requires the Commission, in establishing a special packaging standard, to consider:

a. Available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;

b. The manufacturing practices of industries affected by the PPPA; and

c. The nature and use of the household substance. 15 U.S.C. 1472(b).

These items have been considered with respect to the various determinations made in this notice. (Ref. No. 3.)

E. Effective Date

The PPPA provides that no regulation shall take effect sooner than 180 days or later than one year from the date such regulation is issued, except that, for good cause, the Commission may establish an earlier effective date if it determines an earlier date to be in the public interest. 15 U.S.C. 1471n. Because all loperamide preparations are currently in child-resistant packaging, the Commission concludes that good cause exists for having the regulation take effect 30 days after promulgation of a final rule. Therefore, the rule will become effective 30 days after publication of the final rule, as to all products subject to the rule that are packaged on or after that date. (Ref. Nos. 1 & 3.)

F. Regulatory Flexibility Act Certification

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601 et seq.) generally requires the agency to prepare proposed and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities. The purpose of the Regulatory Flexibility Act, as stated in section 2(b) (5 U.S.C. 602 note), is to require agencies, consistent with their objectives, to fit the requirements of regulations to the scale of the businesses, organizations, and governmental jurisdictions subject to the regulations. Section 605 of the Act provides that an agency is not required to prepare a regulatory flexibility analysis if the head of an agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.

The Commission's Directorate for Economics has prepared a preliminary economic assessment of a rule to require special packaging for loperamide preparations. They concluded that such a requirement would have no effect on current manufacturers and no incremental effect on future manufacturers, since future manufacturers would never have marketed the product in non-child-resistant packaging. Accordingly, for the reasons given above, the Commission concludes that the rule to require special packaging for products containing loperamide will not have any significant economic effect on a substantial number of small entities. (Ref. Nos. 3 & 6.)

G. Environmental Considerations

Pursuant to the National Environmental Policy Act, and in accordance with the Council on Environmental Quality regulations and CPSC procedures for environmental review, the Commission has assessed the possible environmental effects associated with the proposed Poison Prevention Packaging Act (PPPA) packaging requirements for topical drug preparations containing loperamide.

The Commission's regulations at 16 CFR 1021.5(c)(3) state that rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. Analysis of the impact of this rule indicates that CR closures for loperamide preparations will have no significant effects on the environment. This is because the rule will not significantly increase the number of CR closures in use and, in any event, the manufacture, use, and potential disposal of the CR closures present the same potential environmental effects as do the currently used closures.

Therefore, because this rule has no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required. (Ref. Nos. 3 & 6.)

List of Subjects in 16 CFR Part 1700

Consumer protection, Drugs, Infants and children, Packaging and containers, Poison prevention, Toxic substances.

For the reasons given above, the Commission amends 16 CFR part 1700 as follows:

PART 1700—[AMENDED]

1. The authority citation for part 1700 continues to read as follows:

Authority: Pub. L. 91-601, secs. 1-9, 84 Stat. 1670-74, 15 U.S.C. 1471-76. Secs. 1700.1 and 1700.14 also issued under Pub. L. 92-573, sec. 30(a), 88 Stat. 1231.15 U.S.C. 2079(a).

2. Section 1700.14 is amended by adding new paragraph (a)(21) and republishing the introductory text of paragraph (a) to read as follows:

§ 1700.14 Substances requiring special packaging.

(a) *Substances.* The Commission has determined that the degree or nature of the hazard to children in the availability of the following substances, by reason of their packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substances, and the special packaging herein required is technically feasible, practicable, and appropriate for these substances:

* * * * *

(21) *Loperamide.* Preparations for human use in a dosage form intended for oral administration and containing more than 0.045 mg of loperamide in a single package (*i.e.*, retail unit) shall be packaged in accordance with the provisions of § 1700.15(a), (b), and (c).

* * * * *

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of References

(Note: This list of relevant documents will not be printed in the Code of Federal Regulations.)

1. Memorandum from Rita A. Orzel, Ph.D., HSPS, to Virginia A. White, HSPS, "Loperamide Toxicity," March 4, 1992.

2. Memorandum from Charles Wilbur, HSPS, to Rita A. Orzel, Ph.D., HSPS, "Loperamide: Technical Feasibility, Practicability, and Appropriateness Determination," April 1, 1992.

3. Memorandum from Marcia P. Robins, ECSS, to Rita A. Orzel, Ph.D., HSPS, "Preliminary Assessment of Economic and Environmental Effects of a Proposal to Require Child-Resistant Packaging for OTC Drug Preparations Containing Loperamide," April 6, 1992.

4. Briefing Memorandum with attached briefing package, August 6, 1992.

5. Letter from Beverly L. Black, Director, Federal Regulatory Affairs, American Society of Hospital Pharmacists, to Rita Orzel, December 23, 1992.

6. Memorandum from Marcia P. Robins, ECSS, to Rita A. Orzel, Ph.D., HSPS, "Final Regulatory Flexibility Act Analysis for Proposal to Require Child-Resistant Packaging for OTC Drug Preparations Containing Loperamide," February 19, 1993.

7. Memorandum from Jacqueline N. Ferrante, Ph.D., to James F. Hoebel, Acting AED for Health Sciences, "Updated Review of the Children and Poisoning Data Base for Loperamide Ingestions," dated April 29, 1993.

8. Memorandum from Marcia P. Robins, ECSS, to Jacque N. Ferrante, Ph.D., Project Manager, "Market Up-date: Loperamide," dated April 29, 1993.

9. Briefing Memorandum with attached briefing package, June 3, 1993.

[FR Doc. 93-17096 Filed 7-20-93; 8:45 am]

BILLING CODE 6355-01-F

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 2

[Docket No. PL93-3-000]

Policy Statement Regarding Good Faith Requests for Transmission Services and Responses by Transmitting Utilities Under Sections 211(a) and 213(a) of the Federal Power Act, As Amended and Added By the Energy Policy Act of 1992

Issued July 14, 1993.

AGENCY: Federal Energy Regulatory Commission DOE.

ACTION: Final rule; policy statement.

SUMMARY: The Federal Energy Regulatory Commission is adopting guidelines setting forth the elements of what generally constitutes a good faith request for transmission services under sections 211(a) and 213(a) of the Federal Power Act (FPA), as amended and added by the Energy Policy Act of 1992, and of a proper reply to that request. The Commission is issuing this Policy Statement as part of its effort to implement the transmission provisions of the Energy Policy Act of 1992.

DATES: Effective July 14, 1993. Comments may be filed on or before August 20, 1993.

ADDRESSES: Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol St., NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT:

Andre Goodson (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. Telephone: (202) 208-2167

Joseph C. Lynch (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. Telephone: (202) 208-2128

Margaret J. Jess (Technical Information), Office of Economic Policy, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. Telephone: (202) 208-0019.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in room 3104, 941 North Capitol Street NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208-1397. To access CIPS, set your communications software to use 300, 1200, or 2400 bps, full duplex, no parity, 8 data bits, and 1 stop bit. CIPS can also be accessed at 9600 bps by dialing (202) 208-1781. The full text of this rule will be available on CIPS for 30 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, LaDorn Systems Corporation, also located in room 3104, 941 North Capitol Street NE., Washington, DC 20426.

Before Commissioners: Elizabeth Anne Moler, Chair; Vicky A. Bailey, James J. Hoecker, William L. Massey, and Donald F. Santa, Jr.

Policy Statement

Issued July 14, 1993.

I. Introduction

An essential element in implementing sections 211(a) and 213(a) of the Federal Power Act (FPA), as amended and added by the Energy Policy Act of 1992 respectively,[1] is determining what constitutes a good faith transmission request and reply under those sections. This issue is important for two reasons. First, the Commission may not order transmission services under section 211(a) unless the applicant has made a request for such services to the transmitting utility at least 60 days prior to filing an application with the Commission. Second, under section 213(a), unless the transmitting utility agrees to provide transmission services pursuant to a good faith request, at rates, charges, terms and conditions

[1] Public Law 102-486, 106 Stat. 2776 (1992), 16 U.S.C. 824*l*.

acceptable to the requestor, the transmitting utility is required to respond in writing to the requestor within 60 days of receipt of such request or other mutually agreed upon period.

These 60-day requirements make it important that potential section 211(a) applicants, 213(a) requestors, and transmitting utilities have general guidance, as soon as possible, as to what the Commission considers an acceptable transmission request and transmission reply under the newly amended statute. Accordingly, the Commission is adopting this Policy Statement containing such guidelines. The Commission's guidelines are broad enough to encourage individual initiative and negotiation within a flexible framework, leading to accommodations that will encourage optimum access to this country's transmission system.

II. Public Reporting Burden

The Policy Statement establishes new reporting requirements that are the minimum guidelines necessary for a party to request transmission services from a transmitting utility and to ensure the proper response from the transmitting utility. The public reporting burden for these information collections is estimated to average 40 hours per request for the requestor and 160 hours per response for the transmitting utility, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these burden estimates or any other aspect of these collections of information, including suggestions for reducing the burden, by contacting the Federal Energy Regulatory Commission, 941 North Capitol Street, NE., Washington, DC 20426 [Attention: Michael Miller, Information Policy and Standards Branch, (202) 208–1415], and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (Attention: Desk Officer for Federal Energy Regulatory Commission).

III. Background

As amended by the Energy Policy Act, section 211(a) provides that the Commission may not issue an order directing a transmitting utility to provide transmission services unless the person applying for an order has requested the transmission services from the transmitting utility at least 60 days before applying to the Commission. A request for transmission services is, then, a condition precedent to the Commission's ability to order transmission services under section 211 of the FPA.

Section 213(a) of the FPA requires a response by a transmitting utility when any electric utility, Federal power marketing agency, or other person generating electric energy for sale for resale makes a "good faith" request to a transmitting utility[2] to provide wholesale transmission services and requests specific rates and charges, and other terms and conditions of service. Section 213(a) provides that unless the transmitting utility accommodates the request on mutually agreeable terms it shall, within 60 days of receipt of the request, or other mutually agreed upon period, provide the person requesting the services with a detailed written explanation of the basis for the transmitting utility's proposed rates, charges, terms and conditions for such services. The written explanation must also contain an analysis of any physical or other constraints affecting the provision of the requested transmission services. Section 213(a) does not define what is meant by a good faith request for transmission services, nor does the FPA elsewhere contain a definition of the term, and the legislative history of the Energy Policy Act is silent on the subject.

The Commission believes that Congress, in enacting section 213(a) of the FPA, intended that potential applicants for transmission services under section 211 of the FPA and transmitting utilities provide one another with as much information as reasonably available concerning requests for, and ability to provide, transmission services, before a person seeking transmission services avails itself of section 211. The Commission further believes that if potential applicants and transmitting utilities exchange detailed information, this will help to encourage constructive business transactions through negotiated agreements. Accordingly, at this early stage of our administration of sections 211 and 213, we find it appropriate to adopt standards which provide for a broad exchange of information. A broad exchange of information will permit transmission requestors to file focused and more detailed applications under section 211(a) and will allow the Commission to expedite section 211(a) applications. It may also further the goal of encouraging negotiated agreements.

In adopting this Policy Statement, the Commission has read section 211(a) in consonance with section 213(a). On its face, section 211(a) requires that a party need only make "a request" to the transmitting utility. Section 211(a) does not use the adjective "good faith" nor does it require that a section 211(a) applicant specify rates, charges, and other terms and conditions of service when making a request.[3] The Commission believes, however, that for purposes of making a section 211(a) "request," a party's request for transmission services should be the same as a "good faith request" made under section 213(a).[4] If an entity does not make a section 213(a) good faith request 60 days before filing a section 211(a) application, the Commission believes that it has the statutory authority to deny such an application on the basis that a proper request was not made pursuant to section 211(a).

There are several reasons why the Commission finds it appropriate to incorporate the 213(a) good faith requirement as part of what will be deemed to be a satisfactory request under section 211(a). First, because sections 211 and 213 both refer to a 60-day time clock which starts when an entity makes a request for services to a transmitting utility, we believe Congress intended the two sections to work in conjunction with one another. If we were to implement section 211(a) so as to require that a party make only "a request" to a transmitting utility 60 days before filing a section 211 application with the Commission, the two sections would not work in a complementary fashion with one another, because a mere "request" may constitute less than a "good faith" request. Second, requiring two standards—one for "requests" and the other for "good faith requests"—could become administratively burdensome and confusing. Third, if we construed section 211 to require mere "post-card" requests, without requiring that a person requesting transmission services file a good faith request and utilize the "request and response" scenario envisioned by section 213(a), the section 213(a) process could be rendered a nullity. Moreover, it could result in

[2] Section 3(23) of the FPA, as added by the Energy Policy Act, 16 U.S.C. 796(23), defines a "transmitting utility" as any electric utility, qualifying cogeneration facility, qualifying small power production facility, or Federal power marketing agency which owns or operates electric power transmission facilities which are used for the sale of electric energy at wholesale.

[3] Accordingly, as a legal matter the Commission could implement the request requirement under section 211(a) using a more lenient standard than would be used for "good faith" requests under section 213(a). However, as discussed below, as a policy matter we believe it is appropriate to use the same standard.

[4] *See* Section 2.20(a)(2) of the Policy Statement.

requestors and transmitting utilities avoiding or circumventing attempts at negotiation. Likewise, perfunctory responses to requests for transmission services could result in avoiding or circumventing attempts at negotiation.

There is no discussion in the Joint Explanatory Statement of the Committee of Conference to guide us as to whether Congress intended potential section 211 applicants and transmitting utilities to attempt negotiation in order to avoid section 211 proceedings when possible. However, in view of the language, structure, and requirements of section 231(a), we believe that as a policy matter sections 211(a) and 213(a) should be implemented in a manner which encourages negotiation. Therefore, the Commission will adopt standards which: (1) Identify the type of information that would facilitate a section 211(a) request; (2) foster greater competition in wholesale electric markets; (3) encourage coordination and cooperation and (4) encourage negotiated agreements where possible.

This Policy Statement sets forth the elements of what the Commission believes will generally constitute a good faith request under sections 211(a) and 213(a) of the FPA and a proper reply to a good faith request. This proceeding is one of several concurrent proceedings in which the Commission is implementing the transmission provisions of the Energy Policy Act. The other proceedings are: (1) The Commission's Request for Public Comments on the Regional Transmission Group Proposal;[5] (2) Proposed New Reporting Requirements Implementing Section 213(b) of the FPA;[6] and (3) the Commission's inquiry regarding transmission pricing.[7]

This Policy Statement contains only those elements that the Commission would generally look to if a party seeking transmission services were to request an order directing a transmitting utility to provide transmission services under section 211 of the FPA. The Commission encourages those engaged in transmission transactions to devise, on their own initiative, creative ways of solving transmission needs, thus avoiding the delay inevitably resulting from case-by-case resolution by the Commission. The Commission emphasizes that the guidelines set forth in this Policy Statement are neither rigid nor all-encompassing. The Commission encourages negotiation and remains open to suggestions on how to accommodate specific concerns as they arise.

IV. Discussion

A. Components of a Good Faith Request

This Policy Statement contains twelve components of a good faith transmission request. These components are the minimum components that will generally be necessary to provide the transmitting utility with sufficient information so that it can analyze the service request. If a transmitting utility is to be able to analyze a transmission request, the person requesting services must specify the services that it wants. The information that a transmitting utility would need in order to determine how to provide the requested services includes: (1) The identity of the purchaser; (2) assurances that the prospective purchaser of the transmission services is eligible to request the services; and (3) assurances that the Commission is authorized to order the type of services requested under appropriate circumstances.

A good faith request for transmission services should also contain a specific, technical description of the requested services in sufficient detail to permit the transmitting utility to model the additional services on its transmission system. Certain of the technical components of a request for transmission services are discussed below. The others are self-explanatory.

Component (4)—Specifying the Type of Services Requested

Section 211 of the FPA does not place any limit on what is meant by "transmission services," nor does the legislative history suggest any limitation on the nature of the wholesale transmission services the Commission can order under section 211. In the absence of any indication that Congress intended to limit the type of transmission services ordered, any party may request network service under section 211. It is important that the specific language of Component (4) not prevent parties from requesting any type of transmission services, particularly network service. As is the case with any request for transmission under section 211, the Commission will determine whether to order network service on a case-by-case basis.

Although the Commission at this time believes that service more flexible than point-to-point can be ordered under section 211, and thus is a proper subject for good faith requests, parties may submit comments on the limitations, if any, on the Commission's authority to order such service.

The party requesting transmission services should specify the character and nature of the services. The nature of transmission service varies along a continuum, starting with point-to-point service, passing through a form of service that might best be characterized as flexible point-to-point service, and culminating with network service. These terms have no industry-wide accepted definitions. However, the Commission has characterized point-to-point service as involving designated points of entry into and exit from the transmitting utility's system with a designated amount of transfer capability at each point.[8] In a Staff Paper issued with the Commission's recent notice of inquiry concerning transmission pricing, the Commission's staff stated that it understood network service to mean transmission service that allows the user to vary its schedule and points of delivery and receipt on the grid without paying an additional charge for each change.[9]

The Commission invites comments on whether specifying point(s) of receipt and delivery will unduly restrict the ability of parties to request the flexibility of the transmission service that some parties may need. "Network service," for example, involves substantial flexibility in moving power between receipt and delivery points.[10] It is possible that the need for network service will be localized within a control area. An example might be the network service needed by an association of distributors to dispatch their own resources, or by an IPP to sell to multiple buyers. This type of local network service might be combined with flexible point-to-point service to import or export power outside the control area. Alternatively, some parties may wish to request network service over the entire grid of the control area utility, which presumably would involve substantially more flexibility of use. Specifying receipt and delivery

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[5] 57 FR 54,580 (Nov. 19, 1992); 61 FERC ¶61,232 (1992).

[6] 58 FR 17,544 (April 5, 1993); IV FERC Stats. & Regs. ¶32,493 (1993).

[7] Inquiry Concerning the Commission's Pricing Policy for Transmission Services Provided by Public Utilities Under the Federal Power Act. 58 FR 36,400 (July 7, 1993), IV FERC Stats. & Regs. ¶_____.

[8] Entergy Services, Inc., 58 FERC ¶ 61,234 at 61,768 (1992).

[9] *See* Inquiry Concerning the Commission's Pricing Policy for Transmission Services Provided by Public Utilities Under the Federal Power Act, Staff Paper at 13 (Question 18), 58 FR 36,400 (July 7, 1993), IV FERC Stats. & Regs. ¶ _____(1993).

[10] We note that in the Staff Paper issued in conjunction with the Commission's transmission pricing inquiry, *supra* n.9, persons were asked to comment on whether the staff's definition of network service, contained in that paper, is reasonable. Persons wishing to comment on the parameters of "network service" should do so in that docket.

points may not restrict the provision of local network service, but could restrict parties in requesting system-wide network service.

The Commission understands that the network service issue raises important questions, such as how to price the service and what user rights would be associated with it. Some of these will be addressed in the inquiry concerning transmission pricing that the Commission recently initiated.[11] In this proceeding, we ask the following questions:

Question 1. Does the service specification in Component (4) unduly restrict the ability of parties to request the transmission services that they need? If so, what changes would be appropriate?

Question 2. Does the language in Component (4) give owners of transmission facilities sufficient information to provide network service?

Component (5)—The Names of Other Parties Expected To Be Delivering and/or Receiving Power From the Transmitting Utility

If a requesting party knows that it will need to receive services from multiple transmitting utilities, it should provide such information to the transmitting utilities. In instances in which the party requesting services does not know who all the parties will be, however, it should provide whatever information it has and indicate what information is unknown or tentative at the time it makes the request. The transmitting utilities are usually the control area utilities that either are affected by the power flows in question or that would lie on the contract path if two or more transmitting utilities are involved in the transaction. Transmitting utilities need to know which electric control areas will be involved in a transaction.

Component 8—The Expected Transaction Profile

The information supplied by the requesting party and needed by the transmitting utility should be a function of the type of services being requested. Some types of services may require more detailed information than others. The requesting party should provide enough information to permit the transmitting utility to model the power flow impact on its system of both receipts and deliveries. The "expected transaction profile" means the load factor data that describes the flow of power and energy into the transmitting utility's system, *i.e.*, the hourly quantities of power the requesting party would expect to deliver to the transmitting utility's grid at points of interconnection between electric control area utilities, if known.

Component 9—The Degree of Firmness of the Requested Service

The Commission will leave it to the party requesting the services to specify how firm a service is being requested. The degree of firmness of transmission service is often categorized as firm or interruptible. However, these designations may not adequately describe the service that is sought. Therefore, the requesting party should indicate the specific degree of firmness that it seeks. This will help to reduce the likelihood of misunderstandings.

Component 10—Requests Made in Response to Solicitations

Persons requesting service in order to submit a bid in a solicitation for generation resources should state the purpose of the requested service and identify the solicitation for which they are requesting service. Naming the solicitation will be helpful, because some solicitations could result in duplicative transmission service requests. The transmitting utility will be better able to gauge the aggregate amount of service it may have to provide if it can group duplicate requests.

Component 11—The Terms and Conditions Requested

Section 213(a) provides that the requestor must propose rates, terms and conditions for the services it is requesting. We do not think that it is necessary for the requestor to propose the exact, detailed rates, terms and conditions. Rather, a party requesting transmission services can fulfill the rates, terms and conditions requirement by specifying a rate methodology (e.g., embedded or incremental cost), an existing transmission tariff, an existing transmission contract or an existing rate. The Commission does not intend to allow utilities to delay responses to requests for transmission services by taking an overly rigid or technical approach to the "rates, terms and conditions" element of the request. It is sufficient if the one requesting the services has made an effort to develop workable terms and conditions and has proposed what it sees as reasonable rates. The transmitting utility is not bound by the requesting party's proposed rates, terms and conditions. It may reject the proposed rates, terms and conditions and propose its own.

Component 12—Additional Information

Finally, to improve overall effectiveness and efficiency, the party requesting the service should include any information that enhances the transmitting utility's ability to evaluate the request. This can improve the ability to negotiate and lower costs for all parties and will improve chances to arrange for the requested transmission without resorting to section 211 procedures before the Commission.

B. Components of a Reply to a Good Faith Request

This Policy Statement contains five components of a reply to a good faith request for transmission services under section 213(a). These are discussed below.

Component (1)—Acknowledgment of Receipt of the Request

A party requesting transmission services may not seek an order from the Commission under section 211 of the FPA unless it has first requested the transmission services from a transmitting utility 60 days before applying to the Commission. That 60-day period begins to run when the transmitting utility receives the request. A transmitting utility should promptly acknowledge receipt of a request for transmission services. Unless the parties agree on a different time frame for the utility's response, a prompt acknowledgment should occur within 10 days. Receipt of the acknowledgement would alert the one requesting transmission services that its 60-day waiting period has begun.

Component (2)—Requests by the Transmitting Utility for Clarification of Information

The Commission believes that a transmitting utility should be able to ask for clarification of a request if the utility needs more information to evaluate the requested services. In the absence of limitations on requests for such clarifications, however, the processing of requests for transmission could be unduly delayed. Therefore, information clarifications sought by the transmitting utility should be limited to facts needed to evaluate the specific services being requested. A requesting party who believes that a transmitting utility is attempting to frustrate the process by making excessive requests for clarifications can raise this issue when it files a request for a section 211 order with the Commission 60 days after the utility has received its request.

[11] *See* n. 9, *supra*.

Component (3)—The Requirement That the Transmitting Utility Respond Within 60 Days

When the transmitting utility acknowledges receiving a request for transmission services and responds by notifying the party making the request of fees associated with the evaluation of a transmission request, it should specify the date by which it will respond to the request or initiate negotiations that could lead to agreement on some mutually acceptable date other than that set by the 60-day clock. The fees for evaluating transmission service requests should be set based on the cost of processing the request.

Component (4)—The Transmitting Utility's Response If It Believes It Can Provide the Requested Service From Existing Capacity

When a transmitting utility determines that it can provide the requested services from existing capacity, it should proceed to offer the party requesting the services a proposed service agreement covering the service that it will provide. The contract should contain detailed specifications of the price at which the transmitting utility proposes to provide the services.

It is not necessary for the proposed service agreement to contain a regulatory "cost-of-service" study of the kind included in rate filings by public utilities. However, the agreement should explain the basis for the charges for each component of service, including the unbundled components of any transmission rate and any other charges.[12] In other words, the agreement should clearly lay out the charges for each component of the proposed service and the total price the party requesting the service would be expected to pay. Similarly, the agreement should explicitly describe all of the applicable terms and conditions of the transmission services provided under the contract.

The transmitting utility should accompany the agreement with a clear statement of the time during which the offer to provide the transmission services will remain open. The Commission recognizes that an open contract offer obligates the seller while imposing no countervailing obligation on the purchaser, and that an unexecuted contract potentially ties up transmission facilities, thus jeopardizing the availability and price for subsequent requests that would use the same facilities.

On the other hand, entities that might request transmission services may frequently be in the position of bidding on a power solicitation or negotiating other related contracts. In such an instance, the transmission agreement is only one element of the whole transaction, and the purchaser may need to finalize all of the pieces at one time. Under these circumstances, the purchaser might want some sort of reservation or contingency arrangement that would extend the period during which the contract is held open until a time certain or until a set of events reaches completion. Preferably, transmitting utilities and the party requesting the services can be flexible and resolve these problems by mutual agreement. However, the Commission feels that, at a minimum, a transmitting utility should permit the party requesting the service sufficient time to review agreements and coordinate multiple stages of joint transactions.

Component (5)—What the Transmitting Utility Should Do If It Determines That It Must Construct Additional Facilities or Modify Existing Facilities in Order To Provide All or Part of the Requested Services

In situations in which the transmitting utility determines that it must construct additional facilities or modify existing facilities to provide all or part of the requested services, the transmitting utility must provide a fully documented description of why and for how long its grid is and will be constrained. Only by providing full technical information to a person requesting transmission services can a transmitting utility establish a productive working relationship for negotiating transmission service contracts.

In addition to explaining the determination of existing constraints, the transmitting utility should offer the party requesting services an executable contract for a study to determine how the constraint can be relieved. The study contract should specify the cost and production time for the study. The study itself should result in a determination of how the transmitting utility will remove the constraint, how long it will take and how much it will cost.

Transmitting utilities will usually be able to remove constraints by arranging for some type of physical expansion of the transmission grid, but there may be ways short of new construction to meet a request for transmission services. A party requesting services may find an alternate transmission path, or may be able to purchase someone else's prior transmission rights.

Since finding alternative means to accommodate a transmission request may require information available only to the transmitting utility, the Commission urges transmitting utilities to consider ways of making such information available to persons requesting transmission services. One way might be to post existing and planned transmission rights sales on an electronic bulletin board so that the parties can engage in informed negotiations.

If a transmitting utility determines that it can provide part but not all of the requested services without building new facilities, it should offer to provide the part of the services that does not require expansion of its transmission facilities under a separate contract. In effect, the transmitting utility may be able to treat such a request as two separate transactions—one for service on existing facilities and the other as a request involving expansion decisions.

C. Other Issues

1. Prioritization of Service Requests

There is no component regarding how the transmitting utility should prioritize service requests. A transmitting utility may find it difficult to prioritize requests in a fair manner, especially if the transmission grid is near capacity and only a limited number of transmission service requests can be accommodated without expansion. Although the Commission recognizes that "first-come, first-served" prioritization will not always produce the most efficient allocation of capacity, at this time it will accept prioritization based on this procedural rule or any reasonable method of allocation. However, the Commission expects that the industry may develop better allocation mechanisms in the future.

2. The Right of an Applicant to File a Section 211 Request After 60 Days

Good faith requests for transmission services can always be brought to the Commission 60 days after the request is made to the transmitting utility if the party making the request finds the transmitting utility's response unsatisfactory. However, we reiterate that these minimum elements are intended to serve as guidelines; they should not be viewed as limiting the negotiating options available to the parties so long as they do not require Commission action. The Commission urges parties to communicate freely and openly with each other and to work

[12] These components may be capital costs, such as interconnection charges, or variable costs, such as charges for transmission losses, that the transmitting utility proposes to charge for the service.

together creatively and constructively to eliminate constraints and to explore alternative transmission approaches to efficiently coordinate planning for all transmission users.

V. Information Collection Statement

The Office of Management and Budget's (OMB) regulations at 5 CFR 1320.12 require that OMB approve certain information and recordkeeping requirements imposed by an agency. The information collection requirements in this policy statement are contained in new 18 CFR 2.20.

The Commission is issuing this Policy Statement with the information requirements to carry out its regulatory responsibilities to implement the transmission provisions of the Energy Policy Act of 1992. As provided by the Energy Policy Act, section 211(a) provides that the Commission may not issue an order directing a transmitting utility to provide transmission services unless the party requesting such an order has requested the transmission services from the transmitting utility at least 60 days before applying to the Commission. A request for transmission services is, then, a condition precedent to the Commission's ability to order transmission services under section 211 of the Federal Power Act. Section 213(a) of the FPA requires a response by a transmitting utility when any electric utility, Federal power marketing agency, or any other person generating electric energy for sale or resale makes "a good faith" request to a transmitting utility to provide wholesale transmission services under specific rates, charges, terms and conditions of service. The Commission's Office of Electric Power Regulation uses the data for determination of an acceptable transmission request for service of a wheeling order under section 211 of the FPA, and for a determination as to whether a transmitting utility has provided a sufficient reply under the newly amended statute. These collections of information are intended to be the minimum elements needed to make good faith request and a proper response.

The Commission is submitting to the Office of Management and Budget a notification of these proposed collections of information. Interested persons may obtain information on these reporting requirements by contacting the Federal Energy Regulatory Commission, 941 North Capitol Street, NE., Washington, DC 20426 [Attention: Michael Miller, Information Policy and Standards Branch, (202) 208–1415]. Comments on the requirements of this rule can be sent to the Office of Information and Regulatory Affairs of OMB, Washington, DC 20503, (Attention: Desk Officer for Federal Energy Regulatory Commission).

VI. Public Comment Procedures

The Commission invites interested persons to submit written comments on the matters and questions raised in this Policy Statement. An original and 14 copies of the comments must be filed with the Commission no later than August 20, 1993. Comments should be submitted to the Office of the Secretary, 825 North Capitol Street NE., Washington, DC 20426, and should refer to Docket No. PL93–3–000.

All written comments will be placed in the Commission's public files and will be available for inspection in the Commission's Public Reference Room at 941 North Capitol Street NE., Washington DC 20426, during normal business hours.

List of Subjects in 18 CFR Part 2

Administrative practice and procedure, Electric power, Natural gas, Pipelines, Reporting and recordkeeping requirements.

In consideration of the foregoing, the Commission amends part 2, chapter I, Title 18 of the Code of Federal Regulations as set forth below.

By the Commission.

Lois D. Cashell,

Secretary.

PART 2—GENERAL POLICY INTERPRETATIONS

1. The authority citation for part 2 is revised to read as follows:

Authority: 15 U.S.C. 717–716w, 3301–3432; 16 U.S.C. 792–825y, 2601–2645; 42 U.S.C. 4321–4361, 7101–7352.

2. Part 2 is amended by adding § 2.20, to read as follows:

§ 2.20 Good faith requests for transmission services and good faith responses by transmitting utilities.

(a) *General Policy.* (1) This Statement of Policy is adopted in furtherance of the goals of sections 211(a) and 213(a) of the Federal Power Act, as amended and added by the Energy Policy Act of 1992.

(2) Under section 211(a), the Commission may issue an order requiring a transmitting utility to provide transmission services (including any enlargement of transmission capacity necessary to provide such services) only if an applicant has made a request for transmission services to the transmitting utility that would be the subject of such order at least 60 days prior to its filing of an application for such order. The requirement in section 211(a) that an applicant make such a request will be met if such an applicant has, pursuant to section 213(a) of the FPA, made a good faith request to a transmitting utility to provide wholesale transmission services and requests specific rates and charges, and other terms and conditions.

(3) It is the Commission's intention to apply the standards of this Statement of Policy when determining whether and when a valid "good faith" request for service was made.

(4) It is the Commission's intention to encourage an open exchange of information that exhibits a reasonable degree of specificity and completeness between the party requesting transmission services and the transmitting utility.

(5) The Commission intends to apply this Statement of Policy so as to carry out Congress' objective that, subject to appropriate terms and conditions and just and reasonable rates, in conformance with section 212 of the FPA, access to the electric transmission system for the purposes of wholesale transactions be more widely available.

(b) *The Components of a good faith request.* The Commission generally considers the following to constitute the minimum components of a good faith request for transmission services:

(1) The identity, address, telephone number, and facsimile number of the party requesting transmission services, and the same information, if different, for the party's contact person or persons.

(2) A statement that the party requesting transmission services is, or will be upon commencement of service, an entity eligible to request transmission under sections 211(a) and 213(a) of the FPA.

(3) A statement that the request for transmission services is intended to satisfy the "request for transmission services" requirement under sections 211(a) and 213(a) of the FPA, and that the request is not a request for mandatory retail wheeling prohibited under section 212(h) of the FPA.

(4) The party requesting transmission services should specify the character and nature of the services requested. Some types of service may require more detailed information than others. Where point-to-point service is requested, the party requesting transmission services should specify the anticipated point(s) of receipt to the transmitting utility's grid and the anticipated point(s) of delivery from the transmitting utility's grid. Where a party requesting

transmission services requests additional flexibility to schedule multiple resources to meet its needs (*e.g.*, network service), the request for services should contain a description of the requested services in sufficient detail to permit the transmitting utility to model the additional services on its transmission system.

(5) The names of any other parties likely to provide transmission service to deliver electric energy to, and receive electric energy from, the transmitting utility's grid in connection with the requested transmission services.

(6) The proposed dates for initiating and terminating the requested transmission services.

(7) The total amount of transmission capacity being requested.

(8) To the extent it is known or can be estimated, a description of the "expected transaction profile" including load factor data describing the hourly quantities of power and energy the party requesting transmission services would expect to deliver to the transmitting utility's grid at relevant points of interconnection. In the event delivery is to multiple points within the transmitting utility's electric control area, the requestor should describe, to the extent it is known or can be estimated, the expected load (over a given duration of time) at each such delivery point.

(9) Whether firm or non-firm service is being requested. Where a party requests non-firm service, it should specify the priority of service it is willing to accept, or the conditions under which it is willing to accept interruption or curtailment, if known.

(10) A statement as to whether the request is being made in response to a solicitation and a copy of the solicitation if publicly available. This will help the transmitting utility determine whether requests for transmission service are duplicative or mutually exclusive of requests filed by other parties.

(11) The proposed rates, terms and conditions for the requested transmission services as required by section 213(a). It is not necessary for the requestor to propose a specific numerical rate. Rather, a party requesting transmission services can fulfill the rates, terms and conditions requirement by specifying a rate methodology (*e.g.*, embedded or incremental cost) or by referencing an existing formula rate, transmission tariff, or transmission contract. The validity of the good faith request will not depend on the rates proposed by the party requesting transmission services. This requirement is not intended to allow utilities to delay responses to requests for transmission services, or to deny requests for transmission services on the basis of an overly rigid or technical approach to the "rates, terms and conditions" element of the request.

(12) Any other information to facilitate the expeditious processing of its request. Such information will improve the negotiation process, reduce costs, and will improve chances to arrange the requested transmission without resorting to section 211 application procedures before the Commission.

(c) *Components of a Reply to a Good Faith Request.* The Commission generally considers the following to constitute the minimum components of a reply to a good faith request for transmission services under section 213(a):

(1) Unless the parties agree to a different time frame, the transmitting utility must acknowledge the request within 10 days of receipt. The acknowledgement must include a date by which a response will be sent to the party requesting transmission services and a statement of any fees associated with responding to the request (e.g., initial studies).

(2) The transmitting utility may ask the applicant to provide clarification of only the information needed to evaluate and process a "good faith" request. If the person requesting transmission services believes the transmitting utility is attempting to frustrate the process by making excessive requests for clarification, it may raise this issue if, and when, it files a request for a section 211 order with the Commission.

(3) The transmitting utility must respond to a request within 60 days of receipt or some other mutually agreed upon response date. If both parties agree to an alternative schedule, the agreement must be in writing and signed by both parties.

(4) If the transmitting utility determines that it can provide all the requested services from existing capacity, it should respond by offering the party requesting transmission services an executable service agreement that at a minimum contains the following information:

(i) A description of the proposed transmission rate and any other costs. It is not necessary for the proposed service agreement to contain a fully developed cost-of-service. However, the agreement should explain the basis for the charges for each component of service, including the unbundled components of any transmission rate as well as any other charges.

(ii) The proposed service agreement should explicitly describe all of the applicable terms and conditions of the transmission services provided under the agreement.

(iii) The transmitting utility should accompany the proposed service agreement with a clear statement of the time during which the offer to provide the transmission services will remain open. An open agreement offer may obligate the seller while imposing no countervailing obligation on the purchaser, and an unexecuted contract potentially ties up transmission facilities, thus jeopardizing the availability and price for subsequent requests that would use the same facilities. However, at a minimum, a transmitting utility should permit the party requesting transmission services sufficient time to review service agreements and coordinate multiple stages of joint transactions.

(5) If the transmitting utility determines that it must construct additional facilities or modify existing facilities to provide all or part of the requested services, it must:

(i) Identify the specific constraints and their duration that prevent it from providing all the requested services and explain how these constraints prevent it from providing all the requested services or the desired level of firmness.

(ii) Provide to the applicant all studies, computer input and output data, planning, operating and other documents, work papers, assumptions and any other material that forms the basis for determining the constraints.

(iii) Offer to the applicant an executable agreement under which the applicant agrees to reimburse the transmitting utility for all costs of performing any studies necessary to determine what changes to the transmitting utility's grid are needed to overcome the constraint and provide the requested services, their cost, and the estimated time to complete them. At a minimum, the proposed agreement should contain the following:

(A) An estimate of the cost of the study and the time required to complete it, and

(B) A commitment to supply to the party requesting transmission services all computer input and output data, planning, operating and other documents, work papers, assumptions and any other material used to perform the study.

(iv) If a transmitting utility determines that it can provide part but not all of the requested services without building new facilities, it should inform the applicant of any portion of the requested services that can be performed without

constructing additional facilities or modifying existing facilities. In effect, the transmitting utility may be able to treat such a request as two separate transactions—one for service on existing facilities and the other as a request involving expansion decisions. Furthermore, where there are alternative, less expensive means of satisfying all or a portion of a transmission request, the Commission expects the transmitting utility to explore such alternatives (*e.g.*, redispatching certain generating units to alleviate a constraint).

[FR Doc. 93–17216 Filed 7–20–93; 8:45 am]
BILLING CODE 6717–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

Animal Drugs, Feeds, and Related Products; Change of Sponsor Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name and address from Anaquest, Inc., to Anaquest, Inc., A Subsidiary of BOC Health Care, Inc.

EFFECTIVE DATE: July 21, 1993.

FOR FURTHER INFORMATION CONTACT: Judy M. O'Haro, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8737.

SUPPLEMENTARY INFORMATION: Anaquest, Inc., Bernards/78, 110 Allen Rd., Liberty Corner, Bernards Township, NJ 07938, has informed FDA of a change of sponsor name and address to Anaquest, Inc., A Subsidiary of BOC Health Care, Inc., Liberty Corner, NJ 07938–0804. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name and address.

List of Subjects in 21 CFR Part 510

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for "Anaquest, Inc.," and by adding in its place a new entry for "Anaquest, Inc., A Subsidiary of BOC Health Care, Inc.," and in the table in paragraph (c)(2) in the entry for "010019" by revising the sponsor name and address to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * *	*
Anaquest, Inc., A Subsidiary of BOC Health Care, Inc., Liberty Corner, NJ 07938–0804	010019
* * * *	*

(2) * * *

Drug labeler code	Firm name and address
* * * *	*
010019	Anaquest, Inc., A Subsidiary of BOC Health Care, Inc., Liberty Corner, NJ 07938–0804
* * * *	*

Dated: July 13, 1993.

George A. Mitchell,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

[FR Doc. 93–17210 Filed 7–20–93; 8:45 am]
BILLING CODE 4160–01–F

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Neomycin Sulfate Solution

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by The Upjohn Co. The ANADA provides for the oral use of a generic neomycin sulfate solution for the treatment and control of colibacillosis in cattle (excluding veal calves), swine, sheep, and goats.

EFFECTIVE DATE: July 21, 1993.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center For Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8643.

SUPPLEMENTARY INFORMATION: The Upjohn Co., Kalamazoo, MI 49001–0199, filed ANADA 200–113, which provides for the oral use of a generic 200 milligram/milliliter (mg/mL) neomycin sulfate solution (Biosol® liquid) for the treatment and control of colibacillosis (bacterial enteritis) caused by *Escherichia coli* susceptible to neomycin in cattle (excluding veal calves), swine, sheep, and goats. The drug is administered at 10 mg neomycin sulfate per pound of body weight per day in divided doses.

Approval of ANADA 200–113 for The Upjohn Co.'s Biosol® liquid is as a generic copy of The Upjohn's Co.'s NADA 11–315 for Neomix® 325 soluble powder. The ANADA is approved as of June 28, 1993, and the regulations are amended by adding new § 520.1485 (21 CFR 520.1485) to reflect the approval.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows: