intersection of Estelle Mountain Road and Gavilan Springs Ranch Road; then east along an imaginary line to the intersection of Ellis Avenue and Belita Drive; then southeast along an imaginary line to the point of beginning.

* * * * *

Done in Washington, DC, this 24th day of November 1998.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–32076 Filed 11–30–98; 8:45 am]

BILLING CODE 3410–34–P

FEDERAL RESERVE SYSTEM

12 CFR Part 201

[Regulation A]

Extensions of Credit by Federal Reserve Banks; Change in Discount Rate

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors has amended its Regulation A on Extensions of Credit by Federal Reserve Banks to reflect its approval of a decrease in the basic discount rate at each Federal Reserve Bank. The Board acted on requests submitted by the Boards of Directors of the twelve Federal Reserve Banks.

EFFECTIVE DATES: The amendments to part 201 (Regulation A) were effective November 17, 1998. The rate changes for adjustment credit were effective on the dates specified in 12 CFR 201.51.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Johnson, Secretary of the Board (202/452–3259); for users of Telecommunications Device for the Deaf (TDD), please contact Diane Jenkins, (202/452–3544), Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551.

SUPPLEMENTARY INFORMATION: Pursuant to the authority of sections 10(b), 13, 14, 19, *et al.*, of the Federal Reserve Act, the Board has amended its Regulation A (12 CFR part 201) to incorporate changes in discount rates on Federal Reserve Bank extensions of credit. The discount rates are the interest rates charged to depository institutions when they borrow from their district Reserve Banks.

The ''basic discount rate'' is a fixed rate charged by Reserve Banks for adjustment credit and, at the Reserve Banks' discretion, for extended credit. In decreasing the basic discount rate, the Board acted on requests submitted by the Boards of Directors of the twelve Federal Reserve Banks. The new rates were effective on the dates specified below. Although conditions in financial markets have settled down materially since mid-October, unusual strains remain. With the 75-basis-point decline in the federal funds rate since September, financial conditions can reasonably be expected to be consistent with fostering sustained economic expansion while keeping inflationary pressures subdued.

Regulatory Flexibility Act Certification

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Board certifies that the change in the basic discount rate will not have a significant adverse economic impact on a substantial number of small entities. The rule does not impose any additional requirements on entities affected by the regulation.

Administrative Procedure Act

The provisions of 5 U.S.C. 553(b) relating to notice and public participation were not followed in connection with the adoption of the amendment because the Board for good cause finds that delaying the change in the basic discount rate in order to allow notice and public comment on the change is impracticable, unnecessary, and contrary to the public interest in fostering sustainable economic growth.

The provisions of 5 U.S.C. 553(d) that prescribe 30 days prior notice of the effective date of a rule have not been followed because section 553(d) provides that such prior notice is not necessary whenever there is good cause for finding that such notice is contrary to the public interest. As previously stated, the Board determined that delaying the changes in the basic discount rate is contrary to the public interest.

List of Subjects in 12 CFR Part 201

Banks, Banking, Credit, Federal Reserve System.

For the reasons set out in the preamble, 12 CFR part 201 is amended as set forth below:

PART 201—EXTENSIONS OF CREDIT BY FEDERAL RESERVE BANKS (REGULATION A)

1. The authority citation for 12 CFR part 201 continues to read as follows:

Authority: 12 U.S.C. 343 *et seq.*, 347a, 347b, 347c, 347d, 348 *et seq.*, 357, 374, 374a and 461.

2. Section 201.51 is revised to read as follows:

§ 201.51 Adjustment credit for depository institutions.

The rates for adjustment credit provided to depository institutions under § 201.3(a) are:

Federal Reserve Bank	Rate	Effective
Boston	4.5	Nov 18, 1998
New York	4.5	Nov 17, 1998
Philadelphia	4.5	Nov 17, 1998
Cleveland	4.5	Nov 19, 1998
Richmond	4.5	Nov 18, 1998
Atlanta	4.5	Nov 18, 1998
Chicago	4.5	Nov 19, 1998
St. Louis	4.5	Nov 19, 1998
Minneapolis	4.5	Nov 19, 1998
Kansas City	4.5	Nov 18, 1998
Dallas	4.5	Nov 17, 1998
San Francisco	4.5	Nov 17, 1998

By order of the Board of Governors of the Federal Reserve System, November 24, 1998.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 98–31976 Filed 11–30–98; 8:45 am]

BILLING CODE 6210–01–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1700

Poison Prevention Packaging Requirements; Exemption of Sucraid

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission is issuing a rule to exempt from its child-resistant packaging requirements the oral prescription drug Sucraid. Sucraid is a new liquid formulation of sacrosidase, a yeast derived form of the sucrase enzyme, used for the treatment of congenital sucrase-isomaltase deficiency. It was approved by the Food & Drug Administration on April 10, 1998. The Commission has determined that this product is exempt because human experience has shown no evidence of serious toxicity. The Commission takes this action under the authority of the Poison Prevention Packaging Act of 1970.

DATES: The rule will become effective on December 1, 1998.

FOR FURTHER INFORMATION CONTACT: Laura Washburn, Office of Compliance, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 504–0400 ext. 1452.

SUPPLEMENTARY INFORMATION:

A. Background

1. Relevant Statutory and Regulatory Provisions

The Poison Prevention Packaging Act of 1970 (''PPPA''), 15 U.S.C. 1471–1476, authorizes the Commission to establish standards for the ''special packaging'' (also referred to as child-resistant (CR) packaging) of household substances, such as drugs, when CR packaging is necessary to protect children from serious personal injury or illness due to (1) handling, using, or ingesting such substance and (2) the special packaging is technically feasible, practicable, and appropriate for the substance. Accordingly, the Commission requires that oral prescription drugs be in CR packaging. 16 CFR 1700.14(a)(10).

The Commission's regulations allow companies to petition the Commission for exemption from CR requirements. 16 CFR Part 1702. On July 10, 1997, Orphan Medical, Inc. (''Orphan Medical'') petitioned the Commission to exempt its product, Sucraid, from the special packaging requirements for oral prescription drugs. The petitioner stated that the exemption is justified because of lack of toxicity and lack of adverse human experience with the drug. The petitioner also stated that CR packaging is not technically feasible, practicable and appropriate for Sucraid. Because, as explained below, the Commission concluded that Sucraid lacks sufficient toxicity to justify special packaging, the Commission did not consider the technical feasibility, practicability, and appropriateness of special packaging for Sucraid.

2. The Proposed Rule

On June 12, 1998, the Commission issued a notice of proposed rulemaking (NPR) to exempt Sucraid from CR packaging requirements. 63 FR 32159. The Commission did not receive any comments on the proposed exemption.

3. Sucraid

Sucraid is a liquid formulation of sacrosidase, a yeast derived form of the sucrase enzyme. It is used to treat patients with congenital sucrase-isomaltase deficiency (''CSID''). The petitioner estimated that there are approximately 3,000 to 10,000 cases of CSID in the United States. CSID is a condition characterized by absent or low levels of sucrase and isomaltase, two enzymes in the small intestine. Sucrase breaks down sucrose (table sugar) so that it can be absorbed. Persons with CSID have such symptoms as diarrhea, abdominal pain, bloating, and gas. Patients with severe CSID may require hospitalization for diarrhea, dehydration, malnutrition, weakness and muscle wasting. Sacrosidase is an enzyme replacement therapy that reduces the symptoms of CSID.

B. Toxicity Data

Sacrosidase is derived from bakers yeast. It is Generally Recognized as Safe (''GRAS'') for use in food by the Food and Drug Administration (''FDA''). 21 CFR 170.30. Sucraid contains about 1.5 milligrams per milliliter of the enzyme in a 50:50 solution of glycerol and water.

One bottle of Sucraid contains 150 mg of protein, 59 ml of water and 59 ml of glycerol. Similar to dietary proteins, the protein component of Sucraid is digested to amino acids that are used to make new protein and are not expected to cause toxicity. Glycerol is a sweet liquid used as a solvent, preservative, and moisturizer. FDA recognizes glycerol as GRAS for use as a food. 21 CFR 182.1320. It is also used as a drug, for example, to reduce intraocular and intracranial pressure. It also can be used as a laxative.

Possible adverse effects associated with glycerol include nausea, vomiting, headache, and dehydration. Less commonly reported effects include diarrhea, thirst, dizziness, and mental confusion. Some more serious effects have been reported with intravenous administration of glycerol and with certain high risk patients. However, the Hazardous Chemicals Desk Reference indicates that glycerol is only mildly toxic by ingestion. In addition, the Handbook of Common Poisonings in Children characterizes glycerol as a laxative, stating that ''acute exposure to most laxatives produces nausea, vomiting, and diarrhea, which are usually mild and self-limiting.''

The CPSC staff found three cases in the National Electronic Injury Surveillance System (''NEISS'') of children under five years old ingesting products containing glycerol. The products involved were a glycerol suppository, a baby enema preparation, and an ear solution. In all three cases the child was treated and released or examined and released without treatment.

Thus, based on the information discussed above, the glycerol component of Sucraid is not likely to cause significant toxicity to children.

C. Human Experience Data

Investigators conducting clinical trials of Sucraid did not rate any of the adverse effects encountered as probably or definitely related to the drug. Some effects were considered to be possibly related to the drug.

The investigators considered most of the adverse effects to be unrelated to Sucraid and due to illnesses common to children (e.g., flu, ear infection and strep throat). Unrelated effects included sore throat, fever, cough, runny nose, diarrhea, cramping and abdominal pain.

The clinical investigator rated some adverse events as possibly related to Sucraid. These symptoms included abdominal pain, diarrhea, nausea, vomiting, constipation, dehydration, cramps, headache, insomnia, nervousness, and wheezing. The petitioner noted that many of these were gastrointestinal symptoms typical of CSID. Thus, the dose of Sucraid given may not have been adequate to alleviate all symptoms of the disease. An asthmatic child had an acute hypersensitivity reaction (wheezing) to Sucraid that resolved without sequelae. This patient was withdrawn from the trial.

D. Action on the Petition

After considering the information provided by the petitioner and other available toxicity and human experience data, the Commission concludes that the degree and nature of the hazard to children presented by the availability of Sucraid do not require special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting the substance. For these reasons, the Commission has decided to issue the proposed exemption on a final basis.

E. Effective Date

Because the rule issued below provides an exemption, the provisions of 5 U.S.C. 553(c) requiring a delay in the effective date is not applicable. Accordingly, the exemption issued below shall become effective on December 1, 1998.

F. Regulatory Flexibility Act Certification

Under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, an agency that engages in rulemaking generally must prepare proposed and final regulatory flexibility analyses describing the impact of the rule on small businesses and other small entities. 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.

In the proposed rule, the Commission's Directorate for Economic Analysis prepared a preliminary assessment of the impact of a rule to

exempt Sucraid from special packaging requirements. The staff reports that because of the small number of cases of CSID (3,000 to 10,000 in the U.S.), the market for Sucraid is expected to be small. The petitioner, Orphan Medical, is a small manufacturer based on its employment and sales. Orphan Medical has marketing exclusivity for Sucraid for seven years. The exemption from special packaging requirements will allow the company to avoid costs associated with providing CR packaging.

Based on this assessment, the Commission concludes that this regulation exempting Sucraid from special packaging requirements would not have a significant impact on a substantial number of small businesses or other small entities.

G. Environmental Considerations

The Commission's regulations governing environmental review procedures state that exemption of products from requirements for CR packaging under the PPPA normally has little or no potential for affecting the environment. (See 16 CFR 1021.5(c)(3).) The Commission does not foresee any special or unusual circumstances surrounding the exemption issued below. For this reason, the Commission concludes that neither an environmental assessment nor an environmental impact statement is required in this proceeding.

H. Executive Orders

According to Executive Order 12988 (February 5, 1996), agencies must state in clear language the preemptive effect, if any, of new regulations.

The PPPA provides generally that when a special packaging standard issued under the PPPA is in effect, ''no State or political subdivision thereof shall have any authority either to establish or continue in effect, with respect to such household substance, any standard for special packaging (and any exemption therefrom and requirement related thereto) which is not identical to the [PPPA] standard.'' 15 U.S.C. 1476(a). Upon application to the Commission, a State or local standard may be excepted from this preemptive effect if the State or local standard (1) provides a higher degree of protection from the risk of injury or illness than the PPPA standard and (2) does not unduly burden interstate commerce. In addition, the Federal government, or a State or local government, may establish and continue in effect a non-identical special packaging requirement that provides a higher degree of protection than the PPPA requirement for a household substance for the Federal, State or local government's own use. 15 U.S.C. 1476(b).

Thus, with the exceptions noted above, the final rule exempting Sucraid from special packaging requirements preempts non-identical state or local special packaging standards for the substance.

In accordance with Executive Order 12612 (October 26, 1987), the Commission certifies that this regulation does not have sufficient implications for federalism to warrant a Federalism Assessment.

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, 16 CFR part 1700 is amended to read 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 republishing paragraph (a) introductory text and paragraph (a)(10) introductory text, and by adding new paragraph (a)(10)(xx) 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 meeting the requirements of § 1700.20(a) 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:

* * * * *

(10) *Prescription drugs.* Any drug for human use that is in a dosage form intended for oral administration and that is required by Federal law to be dispensed only by or upon an oral or written prescription of a practitioner licensed by law to administer such drug shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c), except for the following:

* * * * *

(xx) Sacrosidase (sucrase) preparations in a solution of glycerol and water.

Dated: November 24, 1998.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

List of Relevant Documents

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

1. Briefing memorandum from Jacqueline Ferrante, Ph.D., EH, to the Commission, ''Petition (PP 97–1) to Exempt Sucraid from the Special Packaging Requirements for Oral Prescription Drugs,'' May 20, 1998.
2. Memorandum from Jacqueline Ferrante, Ph.D., EH, to Mary Ann Danello, Ph.D., Associate Executive Director, EH, ''Sucraid Review,'' April 1, 1998.
3. Memorandum from Marcia P. Robins, EC, to Jacqueline Ferrante, Ph.D., EH, ''Economic Considerations: Petition for exemption from PPPA Requirements for Oral Prescription Drug Sucraid,'' April 2, 1998.
4. Briefing memorandum from J. Ferrante to the Commission, ''Final rule to Exempt Sucraid from CRP requirements, November 12, 1998.''
5. Memorandum from Marcie Robins to J. Ferrante, ''Exemption from CRP requirements for Preparations containing sacrosidase (sucrase): Small Business Effects,'' September 15, 1998.

[FR Doc. 98–31998 Filed 11–30–98; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 11

[Docket No. RM86–2–000]

Update of the Federal Energy Regulatory Commission's Fees Schedule for Annual Charges for the Use of Government Lands

November 24, 1998.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule; update of Federal land use fees.

SUMMARY: On May 8, 1987, the Commission issued its final rule amending Part 11 of its regulations (Order No. 469, 52 FR 18201 May 14, 1987). The final rule revised the billing procedures for annual charges for administering Part I of the Federal Power Act, the billing procedures for charges for Federal dam and land use, and the methodology for assessing Federal land use charges.