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

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

The Commission has considered these items with respect to the various determinations made in this notice, and finds no reason to conclude that the rule is unreasonable.

F. 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.

The Commission does not believe that a shorter effective date is necessary to protect the public interest. Naproxen is currently sold in CR packaging by the companies that have exclusive marketing rights until January 11, 1997. The Commission does not have any indication that significant quantities of naproxen will be marketed in non-CR packaging before a 180 day effective date, with the possible exception of a single size non-CR package as allowed under the PPPA. Thus, the Commission finds that a 180 day effective date is consistent with the public interest. The final rule will apply to products that are packaged on or after the effective date.

G. Regulatory Flexibility Act Certification

When an agency undertakes a rulemaking proceeding, the Regulatory Flexibility Act, 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. 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.

For the proposed rule, the Commission's Directorate for Economics prepared a preliminary economic assessment of a rule to require special packaging for naproxen preparations with 250 mg or more of naproxen in a single package. Based on this assessment, the Commission concluded that such a requirement would not have a significant impact on a substantial number of small businesses or other small entities because the current marketers of naproxen are already using CR packaging and have sole marketing rights for 3 years. Furthermore, the relatively low costs of CR packages should not be an entry burden for future marketers. The Commission received no comments on its preliminary analysis and is not aware of any changes that would affect the Commission's previous conclusion. Thus, the Commission concludes that the rule to require special packaging for naproxen preparations having 250 mg or more of naproxen would not have any significant economic effect on a substantial number of small entities. (8)

H. 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 PPPA requirements for naproxen preparations.

The Commission's regulations state that rules requiring special packaging for consumer products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(3). In connection with the proposed rule, the Commission determined that CR packages for naproxen preparations would have no significant effects on the environment. The Commission is unaware of any developments to change this preliminary assessment. Therefore, because the rule would have no adverse effect on the environment, neither an environmental assessment nor an environmental impact statement is required. (8)

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 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 adding new paragraph (a)(25), 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:

* * * * *

(25) *Naproxen.* Naproxen preparations for human use and containing the equivalent of 250 mg or more of naproxen in a single retail package shall be packaged in accordance with the provisions of § 1700.15 (a), (b), and (c).

Dated: July 24, 1995.

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. Vale, J.A. and Meredith, T.J., Acute poisoning due to non-steroidal anti-inflammatory drugs: clinical features and management. Medical Toxicology 1:12–31, 1986.

2. Memorandum from Terry Kissinger, Ph.D., EPHA, to Jacqueline Ferrante, Ph.D., HSPS, ''Injury Data on Naproxen and Ibuprofen for the 1980–1993 Period,'' May 27, 1994.

3. Memorandum from Charles Wilbur, HSPS, to Jacqueline Ferrante, Ph.D., HSPS, ''Technical Feasibility, Practicability, and Appropriateness Determination for the Proposal to Require Child-Resistant Packaging for OTC Preparations Containing Naproxen,'' June 7, 1994.

4. Memorandum from Marcia P. Robins, ECSS, to Jacqueline Ferrante, Ph.D., HSPS, ''Preliminary Assessment of Economic and Environmental Effects of a Proposal to Require Child-Resistant Packaging,'' September 28, 1994.

5. Memorandum from Sandra Inkster, Ph.D., HSHE, to Jacqueline Ferrante, Ph.D., HSPS, ''Review of Naproxen Toxicity,'' July 17, 1994.

6. Briefing memorandum from Jacqueline Ferrante, Ph.D., HSPS, to the Commission, ''Proposed Special Packaging Standard for Naproxen,'' September 29, 1994.

7. Memorandum from Terry Kissinger, Ph.D., EPHA, to Jacqueline Ferrante, Ph.D., HSPS, ''Update of Injury Data Involving Naproxen and Ibuprofen,'' May 4, 1995.

8. Memorandum from Marcia P. Robins, ECSS, to Jacqueline Ferrante, Ph.D., HSPS, ''Final Regulatory Flexibility Act Analysis: Child-Resistant Packaging for OTC Packages Containing 250 mg or more of Naproxen,'' June 12, 1995.

9. Memorandum from Charles Wilbur, HSPS, to Jacqueline Ferrante, Ph.D., HSPS, ''Technical Feasibility, Practicability, and Appropriateness Determination for the Final Rule to Require Child-Resistant Packaging for OTC Preparations Containing Naproxen,'' May 4, 1995.