period for comments because a rule extending the termination date must be adopted by May 31. The short comment period should not prejudice any party, since parties have already had an opportunity to comment on the need for CRS rules by commenting on the NPRM (and the earlier Advance Notice of Proposed Rulemaking) and in the regulatory review docket. In addition, the extension of the current rules will merely maintain the statue quo. We also note that no one opposed the two earlier extensions of the expiration date and, as indicated, that few parties in this proceeding contend that we should let the rules expire.

Regulatory Impact Analysis

Executive Order 12291 requires each executive agency to prepare a regulatory impact analysis for every "major rule". The Order defines a major rule as one likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of the United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. The CRS regulations appear to be a major rule, since they would probably have an annual impact on the economy of $100 million or more.

Our proposal to change the current rules' termination date to December 11, 1992, would keep in force the existing rules on CRS operations. When the Board conducted its rulemaking, it included a tentative regulatory impact analysis in its notice of proposed rulemaking and made that analysis final when it issued its final rule. In addition, our NPRM contained such a regulatory impact analysis, although that analysis was largely directed at the proposals made by the NPRM. We believe that the Board's analysis, as modified by the NPRM's analysis, remains applicable to our proposal to extend the rules' expiration date and that no new regulatory impact statement appears to be necessary. However, we will consider comments from any parties on that analysis before we make our proposal final.

Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act (Pub. L. 96–354) is designed to ensure that agencies consider flexible approaches to regulation of small businesses and other small entities. It requires regulatory flexibility analyses for rules that, if adopted, would have a significant economic impact on a substantial number of small business entities.

Postponing the rules' termination date to December 11, 1992, will not modify the existing regulation of small businesses. The Board's notice of proposed rulemaking contained an initial regulatory flexibility analysis on the impact of the rules, and the Board discussed the comments on that analysis in its final rule. The Board's analysis appears to be valid for our proposed extension of the rules' termination date. Accordingly, we will adopt the Board's analysis as our tentative regulatory flexibility statement. We will consider any comments filed on that analysis when we decide whether to adopt this proposal.

Paperwork Reduction Act

This proposal will not impose any collection-of-information requirements and so is not subject to the Paperwork Reduction Act, Public Law 96–511, 44 U.S.C. chapter 35.

Federalism Implications

The rule proposed in this notice will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12812, we have determined that the proposed rule does not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

List of Subjects for 14 CFR Part 255

Air carriers, Antitrust, Reporting and recordkeeping requirements.

Accordingly, the Department of Transportation proposes to amend 14 CFR part 255. Carrier-owned Computer Reservation Systems, as follows:

PART 255—CARRIER-OWNED COMPUTER RESERVATIONS SYSTEMS

1. The authority citation for part 255 continues to read as follows:

Authority: Secs. 102, 204, 404, 411, 419, 1102; Public Law 85–726 as amended, 72 Stat. 740, 743, 760, 769, 797; 92 Stat. 1732; 49 U.S.C. 1302, 1324, 1374, 1381, 1389, 1502.

2. Section 255.10 is revised to read as follows:

§ 255.10 Review and termination.

Unless extended, this rule shall terminate on December 11, 1992.

Issued in Washington, DC on May 5, 1992.

Andrew H. Card, Jr.,

Secretary of Transportation.

[FR Doc. 92–10903 Filed 5–6–92; 8:45 am]

BILLING CODE 4910–62–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 355

[Docket No. 80N–0042]

RIN 0905–AA06

Anticaries Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Reopening of Administrative Record

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking; reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is reopening the administrative record for the rulemaking for over-the-counter (OTC) anticaries drug products to include data and information in support of a request to increase the package size limitation for fluoride dentifrice drug products from not more than 260 milligrams (mg) of total fluorine per package to not more than 350 mg. This action is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments by July 7, 1992.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 28, 1980 (45 FR 20666), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC anticaries drug products, together with the recommendations of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. The Panel recommended a package size limitation of not more than 260

milligrams (mg) total fluorine for OTC fluoride dentifrices (45 FR 20666 at 20691).

The agency's proposed regulation, in the form of a tentative final monograph, for OTC anticaries drug products was published in the **Federal Register** of September 31, 1985 (50 FR 39854). In that proposed rule, the agency concurred with the Panel and proposed that OTC fluoride dentifrice packages be limited to not more than 260 mg total fluorine per package (50 FR 39854 at 39872). The agency also proposed that the fluoride ingredients included in OTC fluoride dentifrices be limited to percent concentrations that would be equivalent to 1,000 parts per million (ppm) theoretical total fluorine.

After publication of the tentative final monograph, in 1986 the agency approved a new drug application (NDA 19–518) for an OTC fluoride dentifrice containing 1,500 ppm theoretical total fluorine (Ref. 1). As part of the approval for the NDA, the agency increased the package size limitation from not more than 260 mg of total fluorine per package to not more than 350 mg to accommodate the increased amount of fluoride contained in this dentifrice.

Subsequently, the agency received a citizen petition (Ref. 2) requesting that the administrative record for this rulemaking be reopened and that the tentative final monograph for OTC anticaries drug products be amended to increase the dentifrice package size limitation from not more than 260 mg of total fluorine per package to not more than 350 mg in dentifrice products containing 1,000 ppm theoretical total fluorine. The request was based on the agency's approval of the increased package size under NDA 19–518, as discussed above. The petition included: (1) Published animal toxicology studies that were submitted as part of NDA 19–518, and (2) a statement from FDA's toxicology and pharmacology evaluation of NDA 19–518 in which the agency's reviewer concluded that a package size containing not more than 350 mg fluoride is safe.

FDA has carefully considered the request and believes that it would be appropriate to reopen the administrative record for the rulemaking for OTC anticaries drug products to include the data and information supporting the 350-mg total fluorine dentifrice package size. Based on the supporting toxicology data and the NDA approval, the agency tentatively plans to increase the package size limitation for fluoride dentifrices in § 355.20(a) of the final monograph for OTC anticaries drug products to not more than 350 mg total fluorine. However, the agency is not aware that any dentifrices other than the one product approved under an NDA are currently marketed in package sizes containing greater than 260 mg of total fluorine per package. Therefore, at this time, the agency recommends that manufacturers not implement this increased package size until the final monograph is issued. The agency is currently developing this final monograph. The agency considers that good cause exists, as stated in 21 CFR 330.10(a)(7)(v), at this time to consider new data and information concerning an increase in the dentifrice package size limitation from not more than 260 mg of total fluorine per package to not more than 350 mg.

Interested persons may on or before July 7, 1992, submit to the Dockets Management Branch (address above) written comments regarding increasing the dentifrice package size limitation from not more than 260 mg of total fluorine per package to not more than 350 mg. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

References

(1) Copy of FDA-approved labeling from NDA 19–518, OTC Volume 08LTPTFM, Docket No. 80N–0042, Dockets Management Branch.

(2) Comment No. CP4, Docket No. 85N–0554, Dockets Management Branch.

Dated: May 1, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92–10737 Filed 5–7–92; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 750

[FHWA Docket No. 92–22]

RIN 2125–AC99

Removal of Nonconforming Signs

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FHWA proposes to amend its regulations relating to the removal of nonconforming signs. The recently enacted Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) provides funding for the Federal share of just compensation for the acquisition of nonconforming signs. Consequently, the States are once again required to purchase nonconforming signs to comply with the Highway Beautification Act of 1965. This NPRM discusses several options for ensuring that the Senate provide an effective program for removing nonconforming signs.

DATES: Comments must be received on or before July 7, 1992.

ADDRESSES: Submit written, signed comments to FHWA Docket No. 92–22, Federal Highway Administration, room 4232, HCC–10, Office of Chief Counsel, 400 Seventh Street, SW., Washington, DC 20590. All comments received will be available for examination at the above address between 8:30 a.m. and 3:30 p.m., e.t., Monday through Friday except legal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped envelope.

FOR FURTHER INFORMATION CONTACT: Mr. Marlin E. Meese, Chief, Special Programs and Evaluation Branch, Office of Right-of-Way, HRW–12, (202) 366–2017; or Mr. Robert J. Black, Attorney, Office of Chief Counsel, HCC–31, (202) 366–1359, Federal Highway Administration, 400 Seventh Street SW., Washington, DC 20590. Office hours are from 7:30 a.m. to 4 p.m., e.t., Monday through Friday, except legal Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

The Highway Beautification Act (HBA), Public Law 89–285, 79 Stat. 1028, which was passed in 1965, has always required that signs which are lawfully erected but do not conform to the HBA must be removed five years after the date they become nonconforming. This requirement is found in 23 U.S.C. 131(e). Section 131(n) provides for an exemption from this requirement to the extent that Federal funds have not been made available to participate in the cost of just compensation. The funding authorization for the HBA is contained in 23 U.S.C. 131(m).

Over the years, some $171 million have been made available from General Fund appropriations for removal of signs, and approximately 119,000 nonconforming signs have been removed. The FHWA estimates that about 92,000 nonconforming signs remain to be acquired. Most of these signs have been in place since 1965. Since 1983, no funds have been