

time for final rule implementation; (2) insufficient space on immediate container label of SVP's to state aluminum levels; (3) LVP's that will not meet the 25 µg/L limit without reformulation or repackaging; (4) unavailability of release data required for submission for low production products; (5) labeling SVP's and PBP's with less than 25 µg/L of aluminum; (6) the need for a uniform approach to aluminum testing during stability studies so that the sampling time points for the tests are the same for all products; and (7) clarification that the final rule applies only to LVP, SVP, and PBP drug products used in TPN and not to devices.

Industry and the industry association stated at this meeting that additional time is necessary for moving methods validation from research and development to production, to order and install equipment, and to reduce aluminum levels in raw materials. They also noted that a number of LVP's are in the 50 µg/L of aluminum range rather than the 25 µg/L range; therefore, these products will require repackaging or reformulation to meet the limit.

FDA has included in docket number 90N-0056 a copy of the meeting minutes. As part of the meeting, FDA confirmed the following: (1) That submission of historical batch release or stability data after completion of production of several batches is consistent with the final rule as it exists; (2) that stability testing at time zero and annually thereafter is consistent with the final rule as it exists; (3) that the final rule applies only to LVP, SVP, and PBP drugs used in TPN; and (4) that when a PBP is divided into aliquots of LVP's, the LVP aliquots must meet the 25 µg/L aluminum limit required for all LVP's.

After the meeting, FDA confirmed that § 201.10(i) permits a small package exemption that applies to SVP's with insufficient space on the immediate container label to state aluminum levels.

FDA is issuing this notice to delay the effective date of the rule to address the concerns raised by industry regarding the inability to meet certain requirements of the rule within 1 year.

III. Comment on the Extension of the Effective Date

FDA placed minutes from the meeting described in Section II of this document in Docket No. 90N-0056 shortly after the meeting in June 2000. Those minutes and the memoranda of associated telephone calls set forth in detail the reasons a stay of the effective date for the aluminum rule until January 26, 2003, would be in the public

interest. In particular, the agency is concerned that some products unable to reformulate by the existing effective date are medically necessary and without alternatives thus potentially putting certain patients at great risk. Since the agency is extending the effective date of the aluminum final rule based on the information submitted to it and the safety concerns associated with the potential unavailability of certain medically necessary products it finds, for good cause, that this extension of the effective date of the final rule does not require further notice and comment procedures (5 U.S.C. 553(b); 21 CFR 10.40(e)(1)). More than 6 months have passed since the agency placed supporting information in Docket No. 90N-0056, and the agency has received no adverse correspondence or comments with respect to the request to delay the extension date. In addition, FDA has received several telephone inquiries from other affected parties requesting a delay of the effective date. Therefore, the agency is now extending the effective date of the final rule. However, in accordance with 21 CFR 10.40(e)(1), the agency will accept comment on this extension for a period of 90 days.

Dated: January 18, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 96-115; FCC 99-223]

Telecommunications Carriers' Use of Customer Proprietary Network Information and Other Customer Information

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: The Commission's amendments to its customer proprietary network information (CPNI) rules, which contained information collection requirements, became effective on March 2, 2000.

EFFECTIVE DATES: The amendments to §§ 64.2005, 64.2007 and 64.2009 became effective on March 2, 2000.

FOR FURTHER INFORMATION CONTACT: Jodie Donovan, Attorney Adviser, Common Carrier Bureau, Policy and

Program Planning Division, (202) 418-1580.

SUPPLEMENTARY INFORMATION: On August 16, 1999, the Commission adopted amended rules, pursuant to section 222 of the Communications Act, to protect CPNI and ensure that customers are able to control their personal information from unauthorized use, disclosure and access by common carriers. A summary of these amendments was published in the **Federal Register** (64 FR 53242, October 1, 1999). Because the rules imposed new information collection requirements that had not been approved by OMB, we stated that "the Commission will publish a document in the **Federal Register** announcing the effective dates of these rules." The information collection requirements were approved by OMB on March 2, 2000. See OMB Nos. 3060-0715. Due to an oversight, the Commission failed to publish notice of OMB approval earlier, but we have treated the amendments as effective since March 2, 2000, as anticipated by our order. See Implementation of the Telecommunications Act of 1996, Telecommunications Carriers Use of Customer Proprietary Network Information and Other Customer Information and Implementation of the Non-Accounting Safeguards of section 271 and 272 of the Communications Act of 1934, as Amended, CC Docket Nos. 96-115 and 96-149, 14 FCC Rcd 14409, 14509, para. 207 (1999). This publication therefore satisfies the statement that the Commission would publish a document announcing the effective date of the rules.

List of Subjects on 47 CFR Part 64

Communications common carriers, Reporting and recordkeeping requirements, Telephone.

Federal Communications Commission.

Magalie R. Salas,
Secretary.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 01-92, MM Docket No. 00-186, RM-9970]

Radio Broadcasting Services; Rapid City, South Dakota, Gillette, Wyoming

AGENCY: Federal Communications Commission.

ACTION: Final rule.