

seeks comment on what additional legislative authorities, if any, would be necessary or appropriate to enable FDA to address this issue most effectively.

For interested parties who would like to submit comments on these issues or additional data from any well-conducted scientific studies, we are reopening the comment period of the June 1997 proposal for 30 days. If, after evaluating the comments received on this document, FDA believes that a warning statement on the labels of dietary supplements containing ephedrine alkaloids is necessary to protect the health of individuals consuming such products, the agency will move quickly to publish a final rule requiring the appropriate warning statement and to take any other action we determine to be appropriate.

## II. How to Submit Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify all comments with the docket numbers found in brackets in the heading of this document. You may review received comments in the Dockets Management Branch office between 9 a.m. and 4 p.m., Monday through Friday.

## III. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Bent, S., T. N. Tiedt, M. C. Odden, and M. G. Shlipak, "The Relative Safety of Ephedra Compared with Other Herbal Products," published in the *Annals of Internal Medicine*, March 2003, vol. 138, number 6.

2. Morgenstern, L. B., C. M. Viscoli, W. N. Kernan, L. M. Brass, J. P. Broderick, E. Feldmann, J. L. Wilterdink, T. Brott, and R. I. Horwitz, "Use of Ephedra-Containing Products and Risk for Hemorrhagic Stroke," published in the *Journal of Neurology*, 2003; vol. 60: pp. 132-135.

3. Samenuk, D., M. S. Link, M. K. Homoud, R. Contreras, T. C. Theohardes, P. J. Wang, Estes NA 3d., "Adverse Cardiovascular Events Temporally Associated With ma huang, an Herbal Source of Ephedrine," *Mayo Clinic Proceedings*, 2002, vol. 77(1):12-6.

4. C. A., Haller, P. Jacob 3rd, N. L. Benowitz, "Pharmacology of Ephedra Alkaloids and Caffeine After Single-dose Dietary Supplement Use," *Clinical Pharmacology and Therapeutics*, 2002, June, vol. 71(6), pp. 421-432.

5. Boozer, C. N., J. A. Nasser, S. B. Heymsfield, V. Wang, G. Chen, J. L. Solomon, "An Herbal Supplement Containing Ma Huang-Guarana for Weight Loss: A Randomized, Double-blind Trial," *International Journal of Obesity and Related Metabolic Disorders*, 2001;25(3):316-24.

6. Boozer, C. N., P. A. Daly, P. Homel, J. L. Solomon, D. Blanchard, J. A. Nasser, et. al. "Herbal Ephedra/Caffeine for Weight Loss: a 6-month Randomized Safety and Efficacy Trial," *International Journal of Obesity Related and Metabolic Disorders*, 2002, vol. 26(5): pp. 593-604.

7. Shekelle, P. G, M. L. Hardy, M. Maglione, S. C. Morton, "Ephedra and Ephedrine for Weight Loss and Athletic Performance Enhancement: Clinical Efficacy and Side Effects," Agency for Healthcare Research and Quality (in press).

Dated: February 27, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF AGRICULTURE

### Forest Service

#### 36 CFR Part 219

**RIN 0596-AB86**

#### National Forest Service Land and Resource Management Planning

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice; extension of public comment period.

**SUMMARY:** Notice is hereby given that the public comment period for the proposed rule for National Forest System Land and Resource Management Planning, published in the **Federal Register** on December 6, 2002 (67 FR 72770), is being extended. The original comment period end date was March 6, 2003.

**DATES:** Comments on the proposed rule must be received in writing, on or before the new deadline of April 7, 2003.

**ADDRESSES:** Comments may be sent to USDA FS Planning Rule, Content Analysis Team, PO Box 8359, Missoula, MT 59807; via email to [planning\\_rule@fs.fed.us](mailto:planning_rule@fs.fed.us); or by facsimile

to Planning Rule Comments at (406) 329-3556. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying.

**FOR FURTHER INFORMATION CONTACT:** Jody Sutton, Content Analysis Team Program Coordinator, Forest Service, (801) 517-1023.

**SUPPLEMENTARY INFORMATION:** The Diversity Options Workshop was held February 18-20, 2003, to discuss the approaches to implementing the National Forest Management Act (NFMA) diversity requirement in the proposed rule; address strengths and weaknesses of the two diversity options in the proposed rule; and to discuss any additional options for implementing the NFMA diversity requirement. Proceedings from the Diversity Options Workshop are expected to be posted on World Wide Web at [www.fs.fed.us/emc/nfma](http://www.fs.fed.us/emc/nfma) by March 17, 2003.

Dated: February 26, 2003.

**Bov B. Eav,**

*Acting Chief.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 412

**[CMS-1243-P]**

**RIN 0938-AM41**

#### Medicare Program; Proposed Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient Prospective Payment System

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Proposed rule.

**SUMMARY:** In this proposed rule, we are proposing to change the methodology for determining payments for extraordinarily high-cost cases (cost outliers) made to Medicare-participating hospitals under the acute care hospital inpatient prospective payment system.

Under the existing outlier methodology, the cost-to-charge ratios from hospitals' latest settled cost reports are used in determining a fixed-loss amount cost outlier threshold. We have become aware that, in some cases, hospitals' recent rates of charge