stated hypothesis test(s), population demographics, study site pooling justification, description of statistical tests applied, clear presentation of data and a clear discussion of the statistical results, and conclusions.

In addition to this generalized guidance, the investigator or sponsor is expected to incorporate additional requirements necessary for a well-controlled scientific study. These additional requirements are dependent on what the investigator or sponsor intends to measure or what the expected treatment effect is based on each device's intended use.

E. Clinical Analysis

The analysis which results from the study should include a complete description of all the statistical procedures employed, including assumption verification, pooling justification, population selection, statistical model selection, etc. If any procedures are uncommon or derived by the investigator or sponsor for the specific analysis, an adequate description must be provided of the procedure for FDA to assess its utility and adequacy. Data analysis and interpretations from the clinical investigation should relate to the medical claims.

F. Monitoring

Rigorous monitoring is required to assure that the study procedures are followed and that data are collected in accordance with the study protocol. Forceful monitors, who have appropriate credentials and who are not aligned with patient management or otherwise biased, contribute prominently to a successful study.

III. Opportunity to Request a Change in Classification

Before requiring the filing of a PMA or a notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (b)(2)(A)(iv) of the act and 21 CFR 860.132 to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the act.

A request for a change in the classification of the partially fabricated denture kit is to be in the form of a reclassification petition containing the information required by § 860.123 (21 CFR 860.123), including information relevant to the classification of the device, and shall, under section 515(b)(2)(B) of the act, be submitted by December 14, 1995.

The agency advises that, to ensure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of the partially fabricated denture kit is submitted, the agency will, by January 29, 1996, after consultation with the appropriate FDA advisory committee and by an order published in the Federal Register, either deny the request or give notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the act and 21 CFR 860.130 of the regulations.

IV. References

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

1. Ad Hoc Committee for the Delivery of Quality Prosthetic Care for the Financially Disadvantaged, ''Final Report from the Ad Hoc Committee for the Delivery of Quality Prosthetic Care for the Financially Disadvantaged,'' *Journal of the American Dental Association*, 95:1026–1037, November 1977.

2. Chasens, A. I., ''Controversies in Occlusion,'' Dental Clinics of North America, 34:1:111–123, January 1990.

3. Council on Dental Materials and Devices, ''Association Reports: Partially Prefabricated Dentures,'' *Journal of the American Dental Association*, 98(2):268, February 1979.

4. Council on Dental Materials and Devices, ''Partially Prefabricated Dentures,'' *Journal of the American Dental Association*, 93(2):380, August 1976.

5. Council on Dental Materials and Devices, ''Reports of Councils and Bureaus: Partially Prefabricated Dentures,'' *Journal of the American Dental Association*, 90(3):669, March 1975.

6. Craig, R. G. et al., ''Dental Materials Properties and Manipulation,'' pp. 271–281, 5th ed., Mosby, St. Louis, MO, 1991.

7. Muzyka, B. C., and M. Glick, ''A Review of Oral Fungal Infections and Appropriate Therapy,'' *Journal of the American Dental Association*, 126:63–72, January 1995.

8. Phillips, R. W., ''Elements of Dental Materials For Dental Hygienists and Assistants,'' 3d ed., W. B. Saunders Co., 1977, pp. 130–138.

9. Shay, K., ''Identifying the Needs of the Elderly Dental Patient: The Geriatric Dental Assessment,'' Dental Clinics of North America, 38:3:499, 505–507, July 1994.

10. Vining, R. V., ''Council Comments on Prefabricated Dentures,'' a Letter to the Editor, *Journal of the American Dental Association*, 95:21, July 1977.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this device has been classified into class III since August 12, 1987, and manufacturers of this device legally in commercial distribution before May 28, 1976, or found by FDA to be substantially equivalent to such a device, will be permitted to continue marketing during FDA's review of the PMA or notice of completion of the PDP, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Comments

Interested persons may, on or before February 27, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Interested persons may, on or before December 14, 1995, submit to the Dockets Management Branch a written request to change the classification of the partially fabricated denture kit. Two copies of any request are to be submitted, except that individuals may submit one copy. Comments or requests