hypothesis testing as an acceptable statistical method. Although FDA considers computing p-values to be the correct method to test the hypothesis that a difference exists between the test product and placebo, the agency does not consider this method appropriate for demonstrating noninferiority of the test product to the reference standard. Failure to demonstrate a difference can result from several factors, including a small sample size, inappropriate adjustment, or poor study design. However, it is incorrect to infer from hypothesis testing that two products are equivalent or that one is not inferior to the other. For the comparison between the test product and the reference standard, the agency believes that noninferiority testing, a subset of equivalence testing, is necessary.

The agency is seeking comment on statistical analyses that can be used to support the comparison between the test product and the reference standard. Because statistical testing for demonstrating superiority of a test dentifrice to a placebo dentifrice is generally straightforward, the agency is particularly interested in the statistical testing that would support either equivalence or noninferiority comparisons. Coupled with this, the agency is requesting information on whether the IOA models would require larger sample sizes than the animal caries models.

The agency anticipates that this information-gathering process will be followed by an advisory committee meeting at which the various models and the appropriate statistical analyses will be discussed.

### III. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this notice by January 14, 2002. Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

### IV. References

The following references are on display in the Dockets Management Branch (address above) under Docket No. 80N–0042 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. CP5.
2. Comment No. LET35.
3. Proskin, H. M., N. W. Chilton, and A. Kingman, ''Interim Report of the Ad Hoc Committee for the Consideration of Statistical Concerns Related to the Use of Intra-oral Models in Submissions for Product Claims Approval to the American Dental Association,'' *Journal of Dental Research*, 71:949–952, 1992.
4. Comment No. CP7.
5. Comment No. CP9.
6. Comment No. AMD3.
7. Comment No. CP8.

Dated: September 28, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01–25762 Filed 10–12–01; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### HRSA Aids Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of November 2001.

*Name:* HRSA AIDS Advisory Committee (HAAC).

*Date and Time:* November 1, 2001; 8:30 a.m.–5 p.m., November 2, 2001; 8:30 a.m.–2:30 p.m.

*Place:* Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland 20814, Telephone: (301) 897–9400.

The meeting is open to the public.

*Agenda:* Agenda items for the meeting include reauthorization studies of the Ryan White CARE Act, new CARE Act data requirements, estimating and documenting unmet need, and discussion of HRSA and CDC collaboration.

Anyone requiring further information should contact Joan Holloway, HIV/AIDS Bureau, Parklawn Building, Room 7–13, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–5761.

Dated: October 9, 2001.

**Jane Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 01–25838 Filed 10–12–01; 8:45 am]

BILLING CODE 4165–15–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of November 2001.

*Name:* Advisory Committee on Infant Mortality (ACIM).

*Date and Time:* November 14, 2001; 9 a.m.–5 p.m. November, 15, 2001; 8:30 a.m.–3 p.m.

*Place:* Pooks Hill Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland 20814, (301) 897–9400.

The meeting is open to the public.

*Purpose:* The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department programs which are directed at reducing infant mortality and improving the health status of pregnant women and infants; factors affecting the continuum of care with respect to maternal and child health care, including outcomes following childbirth; factors determining the length of hospital stay following childbirth; strategies to coordinate the variety of Federal, State, and local and private programs and efforts that are designed to deal with the health and social problems impacting on infant mortality; and the implementation of the Healthy Start initiative and infant mortality objectives from *Healthy People 2010.*

*Agenda:* Topics that will be discussed include the following: Early Postpartum Discharge; Low-Birth Weight; Disparities in Infant Mortality; and the Healthy Start Program.

Anyone requiring information regarding the Committee should contact Peter C. van Dyck, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration (HRSA), Room 18–05, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, telephone: (301) 443–2170.

Individuals who are interested in attending any portion of the meeting or who have questions regarding the meeting should contact Ms. Kerry P. Nesseler, HRSA, Maternal and Child Health Bureau, telephone: (301) 443–2170.

Agenda items are subject to change as priorities are further determined.

Dated: October 9, 2001.

**Jane M. Harrison,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. 01–25839 Filed 10–12–01; 8:45 am]

BILLING CODE 4165–15–P