

constitute appropriate OTC drug products.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** a tentative final monograph (TFM) for OTC drug products for the reduction or prevention of dental plaque and gingivitis. Under the OTC drug review procedures, the agency's position and proposal are first stated in the TFM, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

In accordance with § 330.10(a)(2), the Subcommittee and FDA have held as confidential all information concerning OTC drug products for the reduction or prevention of dental plaque and gingivitis submitted for consideration by the Subcommittee. All submitted information will be put on public display in the Dockets Management Branch (*see ADDRESSES*) after June 30, 2003, except to the extent that persons submitting it demonstrate that it falls within the confidentiality provisions of 18 U.S.C. 1905, 5 U.S.C. 552(b), or section 301(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to Robert L. Sherman, Center for Drug Evaluation and Research (*see FOR FURTHER INFORMATION CONTACT*).

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA). Further, any OTC drug products subject to this monograph that are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce unless they are the subject of an NDA or ANDA. Manufacturers are urged to comply voluntarily with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC drug products bearing antiplaque and antiplaque-related claims was issued in the **Federal Register** of September 19, 1990 (55 FR 38560). These claims included the reduction or prevention of plaque, tartar, calculus, film, sticky deposits, bacterial buildup, gingivitis, diseased, inflamed, or swollen gums, pyorrhea, Vincent's disease, periodontal disease, and tooth-destroying acids.

The Commissioner of Food and Drugs appointed the following members of the Dental Products Panel (the Panel) to review the information submitted and to prepare a report under § 330.10(a)(1) and (a)(5) on the safety, effectiveness, and labeling of those products:

Paul B. Robertson, Chairperson
Charles N. Bertolami (resigned March 24, 1997)
William H. Bowen (term ended October 31, 1995)
Carlos E. del Rio (resigned December 14, 1994)
Julianne Glowacki (term ended October 31, 1994)
Deborah Greenspan
Richard D. Norman
Burton Rosan
Christine D. Wu

The Subcommittee, comprised of two members from the Panel plus five nonvoting consultants to the Panel, was subsequently formed to evaluate the submitted data and report its findings on the safety and effectiveness of ingredients for the reduction or prevention of dental plaque and gingivitis. Each of the following was a voting member of the Subcommittee:

William H. Bowen, Chairperson (term ended April 1995)
Robert J. Genco, Chairperson (from April 1995 to December 3, 1998)
Ralph D'Agostino
Max A. Listgarten
Shelia M. McGuire
Eugene D. Savitt
Stanley R. Saxe
Jorgen Slots (resigned April 12, 1995)
Christine D. Wu

Several nonvoting liaison representatives served on the Subcommittee. P. Jean Frazier, served as the consumer liaison until June 6, 1996, followed by Susan Cohen, until May

1997, and Donald S. Altman, on May 27, 1998. Frederick A. Curro, served as industry liaison (drug) until October 31, 1995, followed by Lewis P. Cancro. Gerald N. McEwen, Jr., served as industry liaison (cosmetic) until October 31, 1996.

On August 27, 1997, oversight of the Subcommittee was transferred from the Panel in the Center for Devices and Radiologic Health (CDRH) to the Nonprescription Drugs Advisory Committee in the Center for Drug Evaluation and Research (CDER).

The following FDA employees assisted the Subcommittee:

Carolyn Tollendi served as CDRH Executive Secretary to the Panel until June 7, 1996. Kennerly K. Chapman served as CDER Executive Secretary to the Subcommittee until December 17, 1996, followed by Andrea Neal until May 9, 1997, followed by Rhonda Stover (interim) until May 1998, followed by Kathleen Reedy. Jeanne L. Rippere served as CDER liaison to the Subcommittee until June 7, 1996, followed by Robert L. Sherman. Stephanie A. Mason served as special assistant to the Subcommittee until June 7, 1996.

The Panel and the Subcommittee were first convened on August 2 and 3, 1993, for a joint organizational meeting. Working meetings of the Subcommittee were held on December 16 and 17, 1993; June 28 and 29, October 11, and December 5, 6, and 7, 1994; April 10, 11, and 12, August 14 and 15, and December 4 and 5, 1995; June 6 and 7, and December 16 and 17, 1996; October 29 and 30, 1997; May 27, 28, and 29, October 22, and December 2 and 3, 1998. Joint meetings of the Panel and the Subcommittee were held on August 2 and 3, 1993, and December 6, 1994. Minutes of most Subcommittee meetings are on public display in the Dockets Management Branch (*see ADDRESSES*).

The following individuals appeared before the Panel and/or the Subcommittee at their own or at the Panel's or Subcommittee's request to discuss drug products for the reduction or prevention of plaque and gingivitis: Gariela Adam-Rodwell, Sam Amer, Daniel M. Bagley, John E. Bailey, Michael L. Barnett, Robert D. Bartizek, Kenneth Baumgartner, William J. Blot, Nancy L. Buc, Gregory A. Burkhart, Lewis P. Cancro, James R. Cheever, Philip Cole, W. Greg Collier, Mark M. Crisanti, Catherine C. Davis, Phillip Derfler, John M. DeSesso, Harvey L. Dickstein, Jerry A. Douglass, Matthew J. Doyle, W. Gary Flamm, William E. Gilbertson, Brian F. Gillespie, David M. Graham, Robert Heller, Jane E. Henney,