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INVITED GUEST REVIEW

The ADA guidelines on oral malodor products

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For over 130 years the ADA has been an important information source on the safety and effectiveness of dental products. The Council has recently completed the development of Acceptance Program Guidelines for products used in the management of oral malodor. The ADA Seal Program will ensure that professional and consumer dental products meet rigorous ADA criteria for safety and effectiveness
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Introduction

For over 130 years, the American Dental Association (ADA) has been an important information source on the safety and effectiveness of dental products both for the consumer and the clinician. The ADA Seal of Acceptance Program has assisted the public and profession in making decisions regarding dental therapeutics, materials, instruments, and equipment by its systematic review of product evaluations and testing. There is no other professional evaluation program like it anywhere else in the world. Every day the Association receives inquiries from all over the world requesting information on products, particularly those that have been awarded the ADA Seal of Acceptance. Currently, some 1300 professional and consumer products from more than 320 dental manufacturers display the ADA Seal of Acceptance. Each year the ADA Seal Evaluation program reviews more than 200 products. Using stringent guidelines for reviewing product tests, ingredients, labeling, advertizing, promotional claims, and patient education materials, the program provides the means for the ADA to supply reliable information to the profession and consumers. Furthermore, not every submitted product qualifies for the Seal. The ADA currently rejects about 30% of products when they are initially submitted for the Seal, which attests to the program's rigorous criteria, as well as the overall need for such a program.

History

During the First World War, the USA government asked the National Bureau of Standards to establish national specifications for the purpose of ordering supplies for the military. In addition, the War Department requested a thorough laboratory and clinical investigation of the physical properties of dental amalgam. The Association agreed to participate at the National Bureau of Standards in a collaborative agreement with the government, which has resulted in written specifications for materials used in dentistry. Today, the ADA's Paffenbarger Research Center, located at what is now the National Institute of Standards and Technology, still contributes significantly to the profession's scientific research and new product development.

After World War I, the Association joined with the American Medical Association (AMA) to analyze therapeutic drugs. This collaboration led to the establishment of the Council on Dental Therapeutics (CDT) in 1930. At that time the AMA had an acceptance program that served as a model for the ADA. The ADA's role in dental product evaluation first came to the forefront during the Council's review of information on a product called Pyros. This product claimed to cure 'pyorrhea'. However, the Council found the product to be ineffective and the USA government seized the product and did not allow it to be marketed. A court battle then took place with the final ruling being that the product's assertions were fraudulent. Based on this case, the role of the ADA in evaluating safety and effectiveness of products, reviewing advertizing claims, and informing the profession and public about products was solidified. Later in that year, the CDT developed rigorous guidelines for testing dental products and procured other health care products for evaluation. The ADA Acceptance Program was born. In 1934, the CDT published Accepted Dental Remedies, which became Accepted Dental Therapeutics that was published for many years and has now been replaced by the ADA Guide to Dental Therapeutics.

While this was ongoing the specifications program was continuing at the National Bureau of Standards until 1953. At that time, the International Association for Dental Research (IADR) assumed this responsibility as an advisor to develop specifications for the profession. In 1970, the American National Standards Institute (ANSI) held a national conference and replaced the Specification Committee of the IADR with the newly created American National Standards Committee (ANSC) MD 156. In 2000, the ADA was accredited by ANSI as an Accredited Standards Organization. As a result the current ADA Standards Committee on Dental Products (SCDP) was formed. This committee is responsible for development of all dental standards in the USA. The committee is composed of eight subcommittees: Restorative Materials,

Prosthodontic Materials, Terminology, Instruments, Equipment, Oral Hygiene Products, Implants, and Products for Infection Control. These subcommittees oversee activities of some 60 working groups that are responsible for the development or revision of over 100 ANSI/ADA standards or technical reports. More than 800 volunteers participate in the development of dental standards. The ADA SCDP also considers international standards developed by the International Organization for Standardization (ISO) for adoption as ANSI/ADA specifications. In fact, approximately 80% of current ANSI/ADA standards are also ISO standards. The ADA was very instrumental in the development of ISO/Technical Committee 106, which is responsible for international dental standards. Many of the experts in the ADA SCDP also participate in the activities of ISO/TC 106.

Product evaluation

Standards thus formulated by the ADA SCDP are used in the ADA Seal of Acceptance Program for product evaluation. The ADA has been in business of product testing in its laboratories since the 1920s first at the National Bureau of Standards and since 1966 at the ADA Headquarters in Chicago. The laboratories at the ADA were recently renovated and modernized. Currently some 100 products, both consumer and professional are tested every year for compliance with ANSI/ADA specifications. As mentioned previously, many submitted products fail to meet these criteria. For example, in one recent 18-month period, of the 125 products tested, 57 failed to meet the appropriate standard. In these cases, the Association works with manufacturers to assist in correcting product deficiencies. These efforts have led to changes in labeling, product reformulations, and improvements in quality control. Eventually many of these products have received the ADA Seal.

Guidelines

The Association also evaluates products in its Acceptance Program for which ANSI/ADA standards do not exist. For these products the ADA Council on Scientific Affairs has developed Acceptance Program guidelines. ADA Acceptance Program guidelines developed from the ADA's Provisions for Acceptance, describe in detail the types of laboratory and/or clinical studies needed for Council review of the product. Typically specific procedures for evaluation of physical properties, chemical properties, biocompatibility and most importantly clinical efficacy are included in the guidelines. Currently ADA Acceptance Program Guidelines have been published for over 40 products areas including dental materials, instruments, equipment, therapeutic products, infection control products, and many consumer products such as fluoride dentifrices, toothbrushes, and dental floss.

Oral malodor

Late in 2003, the Council completed the development of Acceptance Program Guidelines for Products Used in the Management of Oral Malodor. The Association began this process because of a growing interest in the public and profession over the prevalence of oral malodor in the adult population and developments in technology and possible treatments. Estimates are that from 25 to 50% of adults suffer from persistent oral malodor and that the condition may rank only behind dental caries and periodontal diseases as the chief complaint of dental patients. Development of the guidelines began in 1998 with the writing of the first draft by the Council and consultants. This draft was submitted to interested parties in 1999 and after review of comments, revised and resubmitted for interested parties review in 2000. At that time it became clear that certain aspects of the guidelines needed further study. The Council decided that a conference should be held to address these concerns. This consensus conference on Diagnosis and Management of Oral Malodor was held at the Association in November 2001. The conference addressed many of the concerns found in the previous interested parties' reviews of the draft guidelines. These included clinical trial design, measurement methods and level of product efficacy and statistical analysis of oral malodor data. In addition, the conference helped in the drafting of a Council statement on oral malodor that was eventually published in the Journal of the ADA in February 2003. Based on the recommendations from the conference the Council revised the guidelines and presented them again for interested party comment in 2002. Additional comments were received again on four major areas: length of clinical trials, initial level of oral malodor in the clinical trials, expected degree of oral malodor reduction in the clinical trials, and number and training of the oral malodor judges. After considerable review and discussion the Council approved the guidelines for publication in late 2003.

The guidelines as published apply to products that are designed to manage oral malodor of non-systemic origin. This type of oral malodor is generated by microorganisms or metabolic compounds that reside on the teeth, tongue or other areas in the oral cavity. Such malodor corresponds to approximately 90% of the observed cases. Products that manage such malodor by either chemical agents or mechanical means may be considered under these guidelines.

Safety of oral malodor products

Regarding safety, the guidelines require that a 6-month study should be conducted unless the product has already been used for plaque and gingivitis control or whose active ingredient is generally recognized as safe. If not, oral flora should be monitored over a 6-month period in appropriately sized clinical study to determine if development of opportunistic and pathogenic organisms occurs. In addition, effects on oral soft and hard tissues should be assessed. As some chemical agents may cause an increase in pathogenic organisms, gingival inflammation should be measured with an appropriate index, e.g. Loe and Silness.

Also evidence should be provided that the product does not adversely affect soft tissues in other ways such as staining. Any evidence of other pathologic conditions such as allergic reactions, oral ulcerations, candidiasis, or secondary infections of the oral mucosa should be noted. For hard tissues and restorative materials, evidence of lack of effects such as staining, shade alterations or loss of structure should be provided. For loss of structure, surface examination may be sufficient. Assessments of possible toxic effects of the active agent or other product factors should be conducted. These should include standard toxicologic profiles, depending on the particular product. Data on the mutagenicity and the carcinogenicity of the product or its active agents must also be submitted. Any patient reports of changes in taste, changes in salivary flow, burning sensations or xerostomia should be reported. Finally, oral flora should be monitored in subjects for the development of opportunistic and pathogenic organisms. Data should be obtained at baseline, 3 weeks and 6 months. Evidence must be provided that significant detrimental shifts in a representative sample of oral flora have not occurred.

Efficacy

According to the ADA guidelines, to demonstrate efficacy in the management of oral malodor, two independent 3-week clinical studies utilizing an appropriate placebo control should be conducted. Either crossover or parallel group designs are permitted. Measurements of oral malodor should be performed at a minimum of two appropriate time periods after baseline during the 3-week period. Significant reductions in oral malodor from baseline to the subsequent timepoints relative to the placebo control should be demonstrated. In addition, 80% of the subjects should demonstrate a reduction to questionable or no oral malodor at some time during the treatment period. Furthermore, evidence should be provided from the previously discussed 6-month clinical study that development of microbial resistance does not occur. Also, mechanism of action should be given (if known).

The guidelines also give substantial information regarding the design of the clinical trials that should be conducted to demonstrate efficacy. Regarding subject selection, the guidelines recommend that individuals should be included who have intrinsic malodor of oral origin and have an average organoleptic intensity rating of at least 2.0 on a 0–5 intensity scale. Subjects with oral diseases such as advanced periodontitis and subjects who smoke or wear oral appliances should be excluded. In addition, as routine professional cleanings may reduce oral malodor, at least 1 week should elapse after a prophylaxis before participation in the study. The guidelines also recommend that measurements of oral malodor be obtained based on product claims. For example, an overnight product should be assessed at day 2 (at a minimum). Regarding oral malodor assessment, organoleptic intensity or hedonic examinations should be performed by two trained and calibrated odor judges. Judges used in the clinical trials should be calibrated using a range of standard odorants sufficient to reflect the different patterns of nose receptors. Instrumental methods may also be used to provide additional data on the level of oral malodor. For example, measurement of volatile sulfur compounds using gas chromatography or portable sulfide monitors is recommended, if available.

Other assessments and labeling

The ADA guidelines give specific information regarding other safety assessments that should be conducted on the product. For example, the microbiologic assessment is described. Also oral soft tissue assessments are needed because some chemical agents may cause an increase in pathogenic organisms. This can be performed by measuring gingival inflammation with an appropriate index such as Loe and Silness. Hard tissue effects are another area of concern. Staining and any decrease in enamel hardness should be assessed.

Finally, the Council took into account its concern about potential misuse and mistreatment by patients using oral malodor products. As part of its requirements for granting the ADA Seal the labeling for the accepted product must contain the following caution statement: 'Persistent oral malodor (bad breath) may indicate a serious underlying disease. If your bad breath persists after 3 weeks of product usage please consult your dentist or physician as soon as possible'.

Seal submission process

The ADA welcomes and encourages product submissions. Besides oral malodor products, the Council considers many professional and consumer products for the ADA Seal. Included are all therapeutic drugs and chemicals used in the diagnosis, treatment, and prevention of oral diseases. The Council also considers dental materials, instruments, and equipment that comply with the ADA's provisions, specifications, or guidelines. Analgesics, anesthetics, fluorides, cavity liners, composite resins, implants, and impression materials are just a few examples of product categories that are included in the Seal Program. Commercial products are evaluated upon the request of a distributor or manufacturer and any company may submit appropriate products to the Council for consideration for acceptance. Although the review process can be complex for some products, many products have received the ADA Seal in <90 days. There is a submission fee for consumer products but no fees are charged for professional products. Once a product is granted the ADA Seal, the acceptance period is for 3 years. Acceptance can be renewed and is usually granted if there are no changes in the product, labeling, or promotional materials.

In conclusion, the ADA Seal ensures that professional and consumer dental products meet the rigorous ADA criteria for safety and effectiveness. With the addition of oral malodor products to the ADA Seal program, consumers can now look for the ADA Seal to help them choose products that have been clearly shown to be efficacious in the treatment of intrinsic oral malodor.