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CLINICAL TESTING OF PERSONAL CARE PRODUCTS

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Abstract

Clinical testing requirements for personal care products (skin cleansers, moisturizers, skin treatment products, shampoos, soaps, *etc.*) are very different from most other products in the U.S. consumer marketplace. These differences dictate the way in which claim substantiation testing of personal care products is carried out. Since personal care products fall into a different classification than drug products, the testing of personal care products are not required to comply with the same standards and protocols used in drug product testing. However, many of the basic tenets of drug product testing are employed. The purpose of this paper is to discuss many of the aspects of the testing of personal care products.

Introduction

The testing of personal care products (skin cleansers, moisturizers, skin treatment products, shampoos, soaps, *etc.*) is unique. Although this class of products is similar to drug products in many ways, they are not regulated in the same way that drug products are regulated (1). This is because personal care products are classified as cosmetic products. The U.S. Food and Drug Administration (FDA) ruled that the difference between a drug and a cosmetic product is what is said about the product. If a product claims to affect the structure and function of the skin, it is legally a drug product (2). Cosmetics are those products that are intended to cleanse, beautify, promote the attractiveness, or alter the appearance of the skin (1). Cosmetic products cannot claim, either directly or indirectly, to affect the structure or function of the skin and remain in the cosmetic category. As long as this artificial barrier is not breached, the U.S. Federal Trade Commission (FTC) instead of the FDA regulates the claims for cosmetic products (3). A thorough review of the regulatory aspects of claims for cosmetic products has been published by J. B. Davis and S. H. McNamara (4).

In the intervening years, the FDA has left that ruling essentially intact. This is not to imply that personal care product companies have not ventured into the drug product category. Indeed, this has happened in many drug product categories. With the establishment of the Over-the-Counter (OTC) category of drug products, personal care products companies have made significant inroads into the drug product category. However, the FDA regulates OTC drug products by a series of monographs that generally specify the type of testing necessary for claims for each class of products (5).

Therefore, aside from the OTC drug products, personal care product companies have significant latitude on the testing required to substantiate the safety and efficacy of a personal care product. That testing must establish the safety of the product as well as demonstrate its claimed efficacy. The level of sophistication required in demonstrating the efficacy of a given personal care product is primarily determined by where the product is being advertised. If the only advertisement is point of purchase printed material, the amount of testing may be minimal. If the product is to be advertised in print ads, such as magazines and newspapers, the level of claim substantiation is higher. The FTC can take regulatory action on any advertising that it believes to be false, misleading, or deceptive (3). Perhaps the most sophisticated level of claim substantiation review for personal care product involves advertisements made on television networks. This medium conducts its own investigation into the testing conducted for products advertised on television. Cable television standards are more lax and less likely to be investigated.

Aside from challenges to claims from the television networks, the primary source of challenges to claims made for personal care products are competitive companies. The National Advertising Division of the Council of Better Business Bureaus (NAD) generally handles these challenges (6). This agency conducts an investigation of the disputed claim (or claims) generally through a series of interrogatives. After evaluating the responses to these questions, the NAD issues an opinion on the disputed claim(s). Although compliance with the NAD opinion is voluntary, the company making the disputed claim generally complies, since the only remaining avenue for resolution of the dispute is through court action which involves considerable money and resources.

Types of Testing Generally Conducted

As mentioned above, the testing of personal care products generally involves tests to ensure the safety of a product as well as to demonstrate its efficacy. The level of sophistication involved in those tests is determined by the way in which the product is to be used and the type(s) of advertising that will be used to promote the product. That level of sophistication increases for

claims made on the product packaging, to claims made in print advertising and, finally, to claims made in television network advertising.

With the advent of cell culture technology, the initial testing on personal care products begins using this method. Cell culture methodology can be used to evaluate the safety and, in some cases, the efficacy of personal care products (7, 8). For instance, the safety of personal care products can be assessed by measuring the number of viable cells from skin cell cultures following either a single or multiple exposures to a product formulation. Other cell culture parameters can be followed, such as the amount of Prostaglandin E2 released by the cultured cells, as a measure of irritancy of product formulations. Similar techniques using corneal cell cultures have been developed to assess the amount of ocular irritation of product formulations (9). These tests, which are predictive but not foolproof, have made it possible to avoid the use of laboratory animals in tests to assess the safety of personal care products. These technologies have made it possible to assess the safety of such products while simultaneously avoiding cruelty to animals and any undesirable encounters with animal rights organizations. Through the use of these cell culture testing techniques, most personal care product marketing companies no longer conduct safety testing on laboratory animals.

Cell culture technology has also been used to demonstrate the efficacy of personal care products, although not to the extent to which they are used in preliminary safety assessments. Techniques have been developed using skin cell cultures to assess the efficacy of skin lightening preparations and sunscreen efficacy, in addition to measuring antioxidant activity and assessing the ability of product formulations to affect the collagen deposition in the skin (10). Undoubtedly, as this technology becomes more sophisticated, methods will be developed for many other effects of personal care products upon the skin.

Since personal care products are developed to be used on human skin, the ultimate demonstration of the safety and efficacy of these products comes from the application of the products to intact human skin. Human volunteers are used to demonstrate the safety of personal care products through the use of Repeated Insult Patch Tests (RIPT), cumulative irritation testing, and other similar test methods (11). These methods generally involve the repeated application of the test product for alternating 24 hour periods of product application and rest. These tests are conducted on a normal skin site on the back or arm, usually under an occlusive or semi-occlusive patch. After removal of the patch material, a trained technician grades the test site for the presence of irritation (redness), usually visually. However, instruments can also be used to measure the amount of redness of the treated site. These techniques provide valuable information on the safety of a personal care product during usage.

The use of human subjects is critical to determining the acceptability of personal care products, as well as the efficacy of formulations. This is because such subjects normally represent the target audience for this class of products. Unless instructed otherwise, the test subjects apply the product to their skin in a manner that simulates how the general public might use it. Furthermore, these subjects can provide verbal feedback about the product that cannot be readily obtained by test methods that do not involve human subjects. Additionally, these subjects can provide invaluable feedback about the safety of the test product under actual usage conditions. This type of information is generally captured through the administration of a test questionnaire at the conclusion of the test, although interim questionnaires can be administered, if necessary. These tests range from a single application technique to multiple use techniques depending upon the information desired. They can be conducted as simulated-use tests in the laboratory or they can be done as in-home placement tests lasting for a week to several months in duration (12).

Such testing generally employs a control in the form of no treatment, a placebo [a formulation without active ingredient(s)] or a competitive product. Testing against a competitive product is sometimes necessary, but is not generally used for claim substantiation because the formulations in personal care products can be rapidly changed by the competitor, thereby invalidating any substantiated competitive claim. It is important that the treatment and control sites be randomized in these types of tests, especially where one extremity or side of the face is used as the test site since the handedness of test subjects can artificially affect the outcome of the test results. Additionally, when using a control on half the face or the arms, randomization of test and control sites becomes critical since the effects of sun exposure can affect the test outcomes. In the U.S., the left side of the body tends to get more sunlight exposure and therefore the resulting sun damage can bias the test results. Some tests use a baseline evaluation as the control, although part of the power of the test is lost under such circumstances. This is because changes in weather conditions can have profound effects on the skin. Those changes cannot be accounted for when this technique is employed.

Although single blind tests are sometimes used when competitive products are employed as a control, double blind testing is seldom, if ever, conducted. This is because the sponsors of these tests are seldom looking for the efficacy of active ingredients in a personal care product. This is generally the purpose of including a placebo into such a test. Furthermore, the type of testing conducted commonly includes an "no treatment" control site. This type of clinical design defeats the purpose of double or single blind testing since the test subject knows which site is untreated and, if the test product exhibits any appreciable efficacy, the test site becomes readily apparent to the laboratory personnel monitoring the test within a relatively limited number of product applications.

The real power in claim substantiation testing of personal care products comes from the use of instruments to objectively assess the efficacy of the test product (13). There are a number of instrumental techniques that could be used. These techniques include an instrument to measure the amount of moisture in the skin by changes in electrical capacitance (14), an instrument to measure changes in the elasticity by measuring the amount of movement of the skin in response to a vacuum applied (15), as well as an instrument to measure changes in the color of the skin via reflected light (16). Other techniques include a method for measuring changes in the skin using image analysis techniques to evaluate the texture of replicas taken from the skin using dental silicone impressions (17), a method for measuring the number of dead skin cells on the skin surface using adhesive tape or cyanoacrylate glue (18), and a method for measuring the amount of oil on the skin using a tape that turns from opaque to transparent in response to the amount of oil present (19). Such instruments and techniques, when used in combination, are exceeding powerful when the test also involves the use of randomized contra-lateral control sites.

Summary

The type of studies employed to substantiate the safety and efficacy of personal care products are only limited by the imagination of the people designing the test and budget of the company sponsoring the test. It is critical that the medium in which the claims are to be used always be kept in mind, since this aspect generally dictates the type of study to be conducted and the level of sophistication needed in analyzing the results. The type of product being evaluated also plays a key role in determining the type of testing to be conducted. Furthermore, the type of competition that a given product will face in the marketplace must also be considered in designing a test for a personal care product. This is especially important when the competitive product makes aggressive claims that will need to not only be met, but also, hopefully, exceeded by the new product being tested.

In testing the safety and efficacy of personal care products, seldom is only one type of test appropriate. Most frequently several tests are conducted under different protocols in order to capture the maximum amount of information. Additionally, these tests may include a variety of objective methods for assessing the efficacy of the test product.

Definitions

From a legal and regulatory standpoint, the term personal care products encompasses a very broad class of consumer products including such things as cosmetics, skin care products, skin treatment products, hair care products, toothbrushes, cotton swabs, feminine hygiene products, and even condoms. The varied aspects of the clinical testing of such a broad class are too great for a single article. Therefore, for the purpose of this article, the term personal care products is defined as those products that are generally recognized by consumers as belonging to this class of products. Such products include cosmetics, skin care products, skin treatment products, soaps and hair care products.

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