Frequently Asked Questions

BioScreen Bulletin: # 2006-02

1. What is the difference between a cosmetic and a drug?

   The Food, Drug, and Cosmetic Act (FD&C Act) defines cosmetics by their *intended* use, as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" [FD&C Act, sec. 201(i)].

   The FD&C Act defines drugs by their *intended* use, as "(A) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease..and (B) articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)].

2. What is required *by law* for cosmetic products?

   The FD&C Act requires that cosmetic products are both SAFE and EFFECTIVE.

   - SAFETY – Substantiation must be done, or the label must read: "Warning– the safety of this product has not been determined" (21CFR 740.10)
   - EFFICACY – Claim substantiation must be done for any cosmetic claims or expiration dating claims that are made
   - Cannot be ADULTERATED or MISBRANDED per FD&C Act, Chapter VI, SEC. 601. [361] and SEC. 602. [362]

   - Ability to HANDLE A RECALL, if necessary

3. What testing is required to *comply* with the law?
   - Safety: Human Patch Test for safety substantiation. Determines the likelihood of increased sensitization or allergy development.
     Eye area safety testing should be done for products to be used around the eyes.
   - Efficacy: Stability Testing required for anything with an active ingredient. Other claims that need substantiation: Wrinkle reduction, Capacitance, Non-comedogenicity, Skin firming, Cell renewal, Anti-inflammatory, Skin lightening, etc.
   - NON-ADULTERATED –Must be free of filth and contaminations whereby it may have been rendered injurious to health. FD&C Act, Chapter VI, SEC. 601. [361]
     Translation: Pathogen free, limited microorganisms
     Testing: Preservative Effectiveness Testing on the formulation, Aerobic Plate Count and Yeast & Mold Testing on each batch
   - NOT MISBRANDED – Labeling may not be false or misleading. FD&C Act, Chapter VI, SEC. 602. [362]
     Translation: Cosmetic or CFR GMPs should be followed (as applicable), and all claims must be found to be true.
     Testing: - Shelf life testing for expiration dating
     - Claim substantiation testing for cosmetic claims

4. What testing is recommended for a lotion or similar water-based product?

   If the lotion is strictly a cosmetic product, with no active ingredients or drug claims, the following is recommended:

   - Repeat Insult Patch Test (RIPT), 50 subjects
   - Antimicrobial Preservative Effectiveness Test (AET) with validation
   - Stability testing with freeze-thaw cycling, AET at the end of both the accelerated and long term study
   - Claim substantiation for any claims such as anti-aging, moisturizing, reduces appearance of fine lines and wrinkles, improves barrier strength, etc.
   - Micro testing such as Aerobic Plate Count and Yeast & Mold on each manufactured batch for QC release testing

5. What if I have active ingredients in my product for sunscreen, acne or any other prevention or treatment?

   If your product contains active ingredients that are recognized by the FDA as drugs, and you are making a drug claim such as Sunscreen, Acne Treatment, etc, then your product is an OTC-Drug product, and all current Good Manufacturing Practices and FDA monographs must be followed. In addition to the safety and micro testing listed above, the following are required by the FDA:

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- Method Validation for any methods used to analyze the active ingredient in your product. Purpose is to determine if the method is able to fully extract and quantify the active from the specific product matrix. Method validation is product specific, not method specific.
- Active ingredient analysis on each manufactured batch for QC release testing
- Stability testing must be done to substantiate expiration dating. After 3 years of real time data is gathered, and the results have passed, it is not necessary to claim an expiration date on the package.

6. What if my product is anhydrous?

   If your product does not contain water, the antimicrobial preservative effectiveness test is not usually appropriate, as a product without water would not likely support the growth of organisms. If you have a question about your specific product, ask to speak with one of our microbiologists. Still, all of the other tests listed would be recommended or required, depending on whether the product is a cosmetic or OTC-Drug product.

7. How do I obtain FDA approval for my product?

   The FDA does not offer approval for cosmetic products or OTC-Drug products where an existing monograph exists. FDA jurisdiction for cosmetic products is in the market, or when importing product into the country. The FDA needs a registration on file for companies manufacturing drug products, and they must be notified of what drug products are being made. FDA may inspect the drug manufacturing facility routinely every two years to assess compliance with cGMP.

8. Can I say that my product has been approved by BioScreen?

   BioScreen offers independent evaluation of products, and issues a report detailing results. These results are usually reported according to set specifications, or a range of acceptable results; however, BioScreen does not issue any type of product approval.

9. Does Does BioScreen offer validated analytical methods?

   According to the FDA, methods must be validated specifically for the formulation that is being analyzed. This is because any of the ingredients in your specific formulation may interfere with detecting and/or quantifying the active ingredient that is being targeted for analysis. BioScreen has in-house methods that have been used to test active ingredients in a variety of formulation, and many of our clients have chosen to have these methods validated for their formulations. There is no way of knowing whether an ingredient in a formulation will interfere with quantifying the active ingredient without validating the method.

10. What is involved with the AET test, and why is validation important?

    The preservative challenge, or Antimicrobial (Preservative) Effectiveness Test, is a 2-part test. First is the validation, where we verify that the preservative system can be neutralized. Next is the challenge, where organisms are added to the product (inoculation) to determine if the preservative system can effectively inhibit the growth of the organisms. The validation takes 3 weeks, and the challenge takes 5 weeks.

    Being able to effectively neutralize the preservative is important to getting accurate results during the challenge phase. In this phase, the product, with the inoculated organisms, is placed in an incubator of ideal temperature for organism growth. At set intervals, we take samples of the product and test them to count the organisms that are still present (those that have not been reduced by the preservative system).

    If the validation has not been done, and we are not neutralizing the preservative during this interval test, the preservative can interfere with accurately detecting the organisms. Without that verification, it's possible that the challenge could show that the product is passing when the preservative system is actually not as effective as it should be.

    In addition, the validation is a compendial requirement, therefore, if this part of the test is not completed, then the test is not considered USP/EP/BP/JP compliant.

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