GUIDE TO INSPECTIONS OF COSMETIC PRODUCT MANUFACTURERS

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I. INTRODUCTION

The purpose of cosmetic inspections is to assure cosmetic product safety and determine whether cosmetics are adulterated or misbranded as defined in Sections 601 and 602 of the FD&C Act.

Prior to any inspection review the current Cosmetic Compliance Program; 21 CFR 700 to 740; district files of the firm to be inspected, including EIRs, consumer complaints, and regulatory actions; and FD&C Act Chapter VI -Cosmetics.

II. COSMETIC PRODUCT

RELATED REGULATORY

REQUIREMENTS AND

HEALTH HAZARD ISSUES

The material included in this section provides background information of pertinent regulatory requirements and consumer safety questions. Familiarize yourself with these issues and cover applicable items during cosmetic EIs.

INGREDIENT LABELING

Cosmetics produced or distributed for retail sale to consumers for their personal care are required to bear ingredient declarations (21 CFR 701.3). Free samples and cosmetics not customarily distributed for retail sale, e.g., hair preparations or make-up products used by professionals at their establishments and skin cleansing or emollient creams used at places of work, are exempt from this requirement provided these products are not also sold to consumers for their consumption at home.

The ingredient declaration must be conspicuous so that it is likely to be read at the time of purchase. It may appear on any information panel of the package, i.e., the folding carton, box or wrapping if the immediate container is so packaged, and may also appear on a firmly affixed tag, tape or card. The letters must not be less than 1/16 of an inch in height - 701.3(b). If the total package surface available to bear labeling is less than 12 square inches, the letters must not be less than 1/32 of an inch in height - 701.3(p). Off-package ingredient labeling is permitted if the cosmetic is held in tightly compartmented trays or racks, it is not enclosed in a folding carton, and the package surface area is less than 12 square inches - 701.3(i).

The ingredients must be declared in descending order of predominance. Color additives (701.3(f)(3)) and ingredients present at one percent or less (701.3(f)(2)) may be declared without regard for predominance. The ingredients must be identified by the names established or adopted by regulation (701.3(c)); those accepted by the FDA as exempt from public disclosure may be stated as "and other ingredients" (701.3(a)).

Cosmetics which are also drugs must first identify the drug ingredient(s) as "active ingredient(s)" before listing the cosmetic ingredients (701.3(d)).

During the inspection, review ingredient declarations in accordance with 21 CFR 701.3 or collect labels for later review. Identify the products not bearing ingredient declaration and determine whether the products are intended for exclusive use by professionals. If an ingredient declaration states "and other ingredients," determine whether the FDA exempted certain ingredients from label disclosure. Attempt to obtain a copy of the letter granting such exemption and attach it to the EIR. Report deficiencies in the EIR under the heading "LABEL REVIEW."

PROHIBITED INGREDIENTS AND OTHER

HAZARDOUS SUBSTANCES

1. Hexachlorophene (21 CFR 250.250)

Because of its neurotoxic effect and ability to penetrate human skin, the use of hexachlorophene (HCP) as a cosmetic ingredient is restricted to use as a preservative where an alternative preservative has not been shown to be as effective. The HCP concentration of the cosmetic may not exceed 0.1%, and it may not be used in cosmetics which in normal use may be applied to mucous membranes.

Check for use of HCP in the manufacture of cosmetics and report in the EIR the name of each HCP containing product, the HCP concentration, and the reasons given for not using another preservative in its place.

2. Mercury Compounds (21 CFR 700.13)

The use of mercury compounds as cosmetic ingredients is limited to use as preservatives in eye area cosmetics at concentrations not exceeding 65 ppm (0.0065%) of mercury calculated as the metal (about 100 ppm or 0.01% of phenylmercuric acetate or nitrate) and provided no other effective and safe preservative is available for use.

Mercury compounds are readily absorbed through the skin on topical application and have the tendency to accumulate in the body. They may cause allergic reactions, skin irritation or neurotoxic manifestations.

Check for use of mercury compounds in the manufacture of cosmetics and determine the kinds and concentrations of compounds used as well as the products in which they are used. Report these findings in the EIR.

3. Chlorofluorocarbon Propellants (21 CFR 700.23

and 2.125)

The use of chlorofluorocarbon propellants (fully halogenated chlorofluoroalkanes) in cosmetic aerosol products intended for domestic consumption is prohibited. The following are fully halogenated chlorofluorocarbons: chlorofluorocarbon 11 (trichlorofluoromethane), chlorofluorocarbon 12 (dichloro-difluoromethane), chlorofluorocarbon 113 (trichlorotri-fluoroethane), chlorofluorocarbon 114 (dichlorotetra-fluoroethane) and fluorocyclobutane C 318

(octofluoro-cyclobutane).

Chlorofluorocarbon-containing cosmetic aerosol products may continue to be manufactured for

export provided they are not in conflict with the laws of the country to which they are to be exported and a control system is being followed which ensures that there is no likelihood, by mistake or otherwise, of diversion of such products into domestic commerce.

Report in the EIR the name of each chlorofluorocarbon-containing aerosol product which is being manufactured or stored at the inspected establishment and determine whether:

a. The manufacturer has an order from the foreign purchaser stating the exact amount desired, that a chlorofluorocarbon be used as propellant, and that he is aware of its illegality in the United States. The manufacturer must also have in his possession a current letter from a responsible official of the country to which the product is to be shipped stating that the use of chlorofluorocarbon propellants is legal in the respective country.

b. The stock of chlorofluorocarbon propellants intended for export production is kept under adequate security at all times.

c. During all stages of manufacture and storage the chlorofluorocarbon-containing aerosol product is kept segregated from all other products and is clearly marked "For Export Only".

d. Complete records are kept accounting for all chlorofluorocarbon propellant use as well as for all manufacture, storage, shipment and exportation of aerosol products containing these propellants. These records must be retained for at least 3 years and made available to any FDA official upon oral or written request.

4. **Other Prohibited Ingredients**

The following additional substances are prohibited as cosmetic ingredients, but not as unintentional contaminants of cosmetics manufactured in accordance with current good manufacturing practices.

a. Bithionol because of its likelihood of causing photocontact sensitization - 21 CFR

700.11.

b. Halogenated Salicylanilides (di-, tri-, metabrom-salan and tetrachlorosalicylanilide) because of their potential of causing photocontact sensitization - 21 CFR 700.15.

c. Chloroform because of its animal carcinogenicity and likely hazard to human health - 21 CFR 700.18.

d. Vinyl chloride as an ingredient of aerosol products because of its carcinogenic effect in humans and animals - 21 CFR 700.14.

e. Zirconium containing complexes in aerosol cosmetic products because of their toxic effect on lungs, including granulomas - 21 CFR 700.16.

f. Methylene chloride as an ingredient of any cosmetic product because of its animal carcinogenicity and likely hazard to human health - 21 CFR 700.19

5. Acetyl ethyl tetramethyl tetralin (AETT)

In a subchronic toxicity study in rats conducted in 1977, AETT was found to cause serious neurotoxic disorders and discoloration of internal organs. It was also determined to penetrate human skin. The fragrance industry voluntarily discontinued the use of AETT in 1978.

Investigate and document any use of AETT in fragrance formulations and finished cosmetic products, usually those claiming to be fragrance free.

6. 6-Methylcoumarin (6-MC)

6-MC, a fragrance ingredient, is a potent photocontact sensitizer which may cause serious skin and systemic disorders in some consumers on contact in the presence of sunlight. Between 1976 & 1978, the FDA received many reports of adverse reactions associated with the use of 6-MC containing suntan preparations. The photocontact allergenicity of 6-MC was subsequently confirmed in clinical studies. In 1978, the FDA asked manufacturers of suntan and sunscreen products to discontinue the use of 6-MC. Two firms voluntarily recalled their 6-MC containing suntan products from the market.

Investigate and document any use of 6-MC in the fragrance of sun exposure products.

7. Musk Ambrette

Musk ambrette, a fragrance ingredient, may cause photocontact sensitization, i.e., allergic reaction of the skin on exposure to musk ambrette and sunlight. Animal studies demonstrated that musk ambrette may cause neurotoxic effects. The International Fragrance Association has recommended that musk ambrette should not be used in products applied to the skin, particularly in products used on skin that is customarily also exposed to sunlight.

Investigate and document any use of musk ambrette in the fragrance of sun exposure products.

8. Nitrosamines

Cosmetics containing as ingredients amines and amino derivatives, particularly di- & triethanolamine (DEA & TEA) may form nitrosamines, if they also contain an ingredient which acts as a nitrosating agent as for example, 2-bromo-2-nitropropane-1,3-diol (Bronopol, Onyxide 500), 5-bromo-5-nitro-1,3-dioxane (Bronidox C) or tris(hydroxymethyl)nitro-methane (Tris Nitro); or if they are contaminated with a nitrosating agent, e.g., sodium nitrite. Amines and their derivatives are mostly present in creams, cream lotions, hair shampoos and cream hair conditioners. The nitrosation may occur during manufacture as well as product storage.

Many nitrosamines have been determined to cause cancer in laboratory animals. They have also been shown to penetrate the skin. Nitrosamine contamination of cosmetics became an issue in early 1977. In a study of 29 cosmetic creams and lotions, N-Nitrosodiethanolamine (NDELA) was determined in 27. The levels of NDELA contamination ranged from less than 10 ppb to 50 ppm. Of the more than 300 cosmetic samples analyzed in 1978, 1979 and early 1980 in FDA laboratories, 7% contained less than 30 ppb NDELA, 26% contained 30 ppb to 2 ppm, and 7% contained between 2 ppm and 150 ppm.

The FDA expressed its concern about the contamination of cosmetics with nitrosamines in a Federal Register notice dated April 10, 1979, which stated that cosmetics containing nitrosamines may be considered adulterated and subject to enforcement action. In surveys of cosmetic products conducted in 1991-92, NDELA was found in 65% of the samples at levels up to 3 ppm.

Investigate whether DEA or TEA containing products contain as ingredients one of the aforementioned nitrosating agents, and report any cosmetic containing these two types of ingredients. When collecting surveillance samples, select such products for chemical analysis.

9. Dioxane

Cosmetics containing as ingredients ethoxylated surface active agents, i.e., detergents, foaming agents, emulsifiers and certain solvents identifiable by the prefix, word or syllable "PEG," "Polyethylene," "Polyethylene glycol," "Polyoxyethylene," "-eth-," or "-oxynol-," may be contaminated with 1,4-dioxane. It may be removed from ethoxylated compounds by means of vacuum stripping at the end of the polymerization process with out an unreasonable increase in raw material cost.

In rodent feeding studies conducted for the National Cancer Institute, 1,4-dioxane was found to produce cancer of the liver and the nasal turbinates. It also caused systemic cancer in a skin painting study. Skin absorption studies demonstrated that dioxane readily penetrates animal and human skin from various types of vehicles. However, it was also determined that most of the dioxane applied to the skin in a vehicle evaporates into the environment and may not be available for skin absorption.

The contamination of ethoxylated surface-active agents with dioxane was first reported in 1978. Many of the raw materials analyzed since then have been found to contain dioxane; some contained as much as, or more than, 100 ppm. In finished cosmetic products containing ethoxylated surface-active agents, the incidence and level of dioxane contamination was significantly lower.

TAMPER-RESISTANT PACKAGING

Cosmetic liquid oral hygiene products, e.g., mouthwashes and breath fresheners, and any kind of vaginal product introduced into interstate commerce after February 6, 1984, must be packaged in tamper-resistant packages if intended to be accessible to the public while held for retail sale - 21 CFR 700.25.

A tamper-resistant package may be an immediate container and closure system or an outer (secondary) container system which has an indicator or barrier to entry and which provides visible evidence to consumers that tampering has occurred when its indicator or barrier to entry has been breached or is missing. To prevent substitution of the tamper-resistant feature after tampering, the indicator or barrier to entry must be distinctive by design (e.g., an aerosol container or breakable cap) or by use of an identifying characteristic (e.g., name, pattern or logo on cap or carton seal).

In addition, a tamper-resistant package other than an aerosol package must bear a prominently placed label statement which alerts the consumer to the tamper-resistant feature of the package and which is not affected when the tamper-resistant feature is breached or missing. Example: "For your protection, this bottle has an imprinted seal around the neck."

If cosmetics are manufactured requiring tamper-resistant packaging, check whether the indicator or barrier to entry is distinctive by design or bears an identifying characteristic which cannot readily be duplicated by the public and whether the label statement properly alerts the consumer to the tamper-resistant feature and is appropriately placed.

ADEQUACY OF PRESERVATION

Cosmetics need not be sterile, however, they must not be contaminated with microorganisms which may be pathogenic, and the density of non-pathogenic microorganisms should be low. In addition, cosmetics should remain in this condition when used by consumers. Some cosmetics, i.e., those containing more than about 10% ethanol, propylene glycol, glycerol, etc., and cosmetics in self-pressurized containers, are self-preserving and are not likely to become contaminated with microorganisms.

The hazard of inadequately preserved cosmetics to human health has been amply demonstrated by

reports of staphylococcal infections in hospitals from use of contaminated hand creams and hand lotions and the studies conducted on eye area cosmetics. Regardless of whether a cosmetic becomes contaminated during manufacture or during consumer use, the hazard is twofold, namely, (1) the direct effect of microorganisms on human health and (2) the circuitous effect on human health due to product contamination and spoilage, product separation, or formation of harmful microbial metabolites.

Microbial contamination of cosmetics during manufacture was a major issue during the 1960's and early 1970's. Since then, significant progress has been made by the cosmetic industry towards implementation of sanitary manufacturing practices, more rigorous microbiological control, and the development of better-preserved cosmetic products. However, the problem of adequacy of preservation of cosmetics to prevent contamination during consumer use continues to be of concern to the Agency, particularly with respect to cosmetics coming into contact with the eye.

The studies conducted to determine the hazard associated with inadequately preserved eye area cosmetics revealed that microbial contamination of new mascaras was rare but that many became readily contaminated with the microorganisms found on the eyelids and fingers of consumers. If an inadequately preserved mascara becomes contaminated with Pseudomonas aeruginosa and the delicate cornea of the eye is scratched with the applicator, the eye may become infected. P. aeruginosa is an ubiquitous microorganism which may also occasionally be present on the skin. Corneal ulceration may lead to partial or total blindness in the injured eye. Several cases of corneal ulceration and blindness associated with Pseudomonas contaminated mascaras have been identified. Eye area cosmetics contaminated with Staphylococcus epidermidis or other cocci may cause conjunctivitis or blepharitis.

The issue of adequacy of preservation of eye area cosmetics was addressed in the Federal Register notice of October 11, 1977. The Agency announced its intention to propose regulations and invited interested persons to submit information on microbial testing methods and standards of performance suitable to ensure that such cosmetics do not become contaminated with microorganisms during manufacture and use by consumers. Since no useful information was received about such methods, standards for determining adequacy of preservation are now being developed for the Agency under contract. The notice also stated that "FDA does not intend to await the completion of the rulemaking pronounced in this notice of intent before taking needed regulatory action."

In addition to the inspection of an establishment for sanitary storage and handling of raw materials and for sanitary manufacture of finished products, determine, whether:

a. Each batch of cosmetic which is not self-preserving is tested for microbial contamination before a batch is released for interstate shipment, and

b. Each cosmetic, particularly each eye area cosmetic, has been tested during product development for adequacy of preservation against microbial contamination which may occur under reasonably foreseeable conditions of consumer use.

Review the qualitative and quantitative composition of the preservative system of each eye area cosmetic. Report findings in the EIR. When collecting surveillance samples, select eye area cosmetics over creams or cream lotions.

AEROSOL PRODUCTS

Chlorofluorocarbon propellants, vinyl chloride, and zirconium compounds are prohibited as ingredients of cosmetic aerosol products - 21 CFR 700.23, 700.14 and 700.16.

Cosmetic aerosol products must bear the following label statement (21 CFR 740.11(a)(1)):

Warning - Avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120o F. Keep out of reach of children.

Hydrocarbon propellant-containing products also must bear the statement (21 CFR 740.11(b)(1)):

Warning - Use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

Exempt from the second warning requirement are:

a. Foam or cream products containing less than 10% propellant.

b. Products in a container with a physical barrier that prevents escape of the propellant at the time of use.

c. Products of a net quantity of contents less than 2 ounces and equipped with a metering valve.

d. Products with a net quantity of contents less than 1/2 ounce.

Review labels of aerosol products for compliance with these requirements and report any deviation.

FEMININE DEODORANT SPRAYS

Products whose labeling states or suggests that the product is for use in the female genital area or for use all over the body must bear the following label statement - 21 CFR 740.12:

Caution - For external use only. Spray at least 8 in. from skin. Do not apply to broken, irritated, or itching skin. Persistent, unusual odor or discharge may indicate conditions for which a physician should be consulted. Discontinue use immediately if rash, irritation, or discomfort develops.

Feminine deodorant sprays which are not packaged in self-pressurized containers, need not bear the sentence "Spray at least 8 inches from skin." If they are aerosol products, they must also bear the warning required at 21 CFR 740.11(a)(1). Additionally, if the propellant is a hydrocarbon, the label must bear the warning required at 740.11(b)(1).

Review labels for compliance with these requirements and report any deviation.

CHILDREN'S FOAMING DETERGENT BATHS

(BUBBLE BATH PRODUCTS)

The risk associated with certain conditions of use of foaming detergent bath products, i.e., bubble bath products, particularly excessive or prolonged exposure, has been known for some time. Over the years, the agency has received numerous complaints from consumers and physicians about itching, rashes and urinary tract disorders. Reports in the medical literature have mentioned that the adverse reactions have either subsided or disappeared when the use of bubble bath products was discontinued. Most adverse reactions appeared to have been caused by inadvertent product misuse which may not have occurred if consumers had been given proper directions for safe use of these products and had been cautioned about the possible adverse effects by means of mandatory label warning.

21 CFR 740.17 requires that children's foaming detergent bath products, i.e., children's bubble bath products, and all foaming detergent bath products not labeled as intended for use exclusively by

adults, distributed after June 5, 1987, bear adequate directions for safe use and the following caution:

Caution - Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue if rash, redness, or itching occur. Consult your physician if irritation persists. Keep out of reach of children.

For the purpose of this regulation, a foaming detergent bath product (bubble bath product) is defined as any product intended to be added to the bath for the purpose of producing foam and containing a surface-active agent serving as a detergent or foaming agent.

Examples of label statements properly identifying a product as being intended for use exclusively by adults are: "Keep out of reach of children." or "For adult use only."

Determine whether bubble bath products bear adequate directions for safe use and the caution statement required by regulation. Review consumer complaints for adverse reactions associated with bubble bath products. Report findings in the EIR.

HAIR DYE PRODUCTS

Hair dye products may be divided into three categories, i.e., permanent, semi-permanent and temporary hair colors. Permanent hair colors are the most popular hair dye products. They may be further divided into oxidation hair dyes and progressive hair dyes. Oxidation hair dye products consist of a solution of dye intermediates, e.g., p-phenyl- enediamine (which form hair dyes on chemical reaction), and preformed dyes, e.g., 2-nitro-p-phenylenediamine (which already are dyes and are added to achieve the intended shades), in an aqueous, ammoniacal vehicle containing soap, detergents and conditioning agents, and a solution of hydrogen peroxide, usually 6%, in water or cream lotion. The ammoniacal dye solution and the hydrogen peroxide solution, often called the developer, are mixed shortly before application to the hair. The applied mixture causes the hair to swell, and the dye intermediates (and preformed dyes) penetrate the hair shaft to some extent before the chemical reaction forming the hair dye is complete.

Progressive hair dye products contain lead acetate as the active ingredient. Lead acetate is approved as a color additive for coloring hair on the scalp at concentrations not exceeding 0.6% w/v, calculated as metallic lead (21 CFR 73.2396). Bismuth citrate, the other approved color additive (21 CFR 73.2110), is used to a much lesser extent. Progressive hair dyes change the color of hair gradually from light straw color to almost black by reacting with the sulfur of hair keratin as well as oxidation on the hair surface.

Semi-permanent and temporary hair coloring products are solutions (on rare occasions dry powders) of various coal-tar dyes, i.e., synthetic organic dyes, which deposit and adhere to the hair shaft to a greater or lesser extent. Temporary hair colors must be re-applied after each shampooing. The vehicle may consist of water, organic solvents, gums, surfactants and conditioning agents. The coal-tar dyes are either approved, listed and certified color additives or dyes for which approval and listing has not been sought. The dyes may not be non-permitted metallic salts or vegetable substances.

If a hair dye product contains a non-approved coal-tar color (but not a non-approved metallic or vegetable dye), and even if this coal-tar color is known to cause adverse reactions under conditions of use, the product may not be considered adulterated if the label bears the caution statement provided in Section 601(a) of the FD&C Act and offers adequate directions for preliminary patch testing by consumers for skin sensitivity. The caution statement reads as follows:

Caution - This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not

be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.

If the label of a coal-tar color containing hair dye product does not bear the caution statement of Section 601(a) and the patch testing directions, it may be subject to regulatory action if it is determined to be harmful under customary conditions of use.

Several coal-tar hair dye ingredients have been found to cause cancer in laboratory animals, as for example, 4-methoxy-m-phenylenediamine (4-MMPD, 2,4-diaminoanisole). Additionally, studies in humans and monkeys have demonstrated that 4-MMPD readily penetrates the skin. The Agency considered the risk associated with the use of hair dyes containing 4-MMPD a "material fact" which should be known to consumers and published in October 1979 a regulation requiring a label warning on hair dye products containing 4-MMPD which was to become effective April 16, 1980. The regulation required that hair dyes containing 4-MMPD bear the following warning:

Warning - Contains an ingredient that can penetrate your skin and has been determined to cause cancer in laboratory animals. Some hair dye manufacturers held that the potential risk was too small to be considered "material" and challenged the validity of the regulation in court. The Agency decided to reconsider its earlier position and entered into a consent agreement with the hair dye manufacturers. The effective date of the regulation has been stayed until completion of the assessment of the carcinogenic risk of 4-MMPD in accordance with scientifically accepted procedures.

In addition to 4-MMPD, the following other hair dye ingredients have been reported to cause cancer in at least one animal species in lifetime feeding studies: 4-chloro-m-phenylenediamine, 2,4-toluenediamine, 2-nitro-p-phenylene-diamine and 4-amino-2-nitrophenol. They also were found to penetrate human and animal skin.

Determine whether the manufactured hair dye products contain 4-MMPD, non-listed metallic salts or vegetable substances as dye ingredients. Also identify and report hair dye products not bearing the caution statement of Section 601(a) and containing a non-listed (non-approved) coal-tar color.

DEPILATORIES AND HAIR STRAIGHTENERS

Chemical depilatories are highly alkaline pastes, creams or cream lotions containing either alkali or alkali-earth sulfides (usually up to 35% barium or strontium sulfide) or mixtures of alkali-earth hydroxides (usually 5-10% calcium hydroxide) and salts of aliphatic mercapto acids (usually 2-5% calcium thioglycolate). These ingredients cause degradation of hair keratin and deterioration of hair fibers to a jelly-like mass that can easily be removed by wiping or scraping. The pH of chemical depilatories usually falls between 10 and 12.5.

Hair straighteners are mostly creams or cream lotions containing either up to about 3% sodium hydroxide or, as a kit, a lotion containing about 5% calcium hydroxide and a solution of up to about 30% guanidine carbonate. The pH is around 12. Some straighteners contain about 4% ammonium thioglycolate as the active ingredient.

Because improperly formulated or incorrectly used depilatories or hair straighteners may cause serious skin irritation, they should be thoroughly tested for safety, be subjected to careful quality control during manufacture, and provide explicit warnings and directions for safe use.

Review labeling for appropriate warnings and directions for safe use, investigate quality control procedures, obtain information on consumer injury complaints, and report findings in EIR.

HAIR SHAMPOOS, RINSES, CONDITIONERS

Hair shampoos contain anionic or ampholytic detergents serving as cleansing and foaming agents; rinses and conditioners may contain cationics (quaternary ammonium compounds) serving as antistatic agents. When inadvertently introduced into the eye, these surface active agents may cause stinging, mucosal irritation or even corneal damage, and products contaminated with microorganisms may cause infection. If the cornea has been scratched or otherwise damaged, pathogenic microorganisms, particularly Pseudomonas aeruginosa, may cause corneal ulceration and blindness. Cosmetic hair products may be adequately preserved with, for example, formaldehyde releasing preservatives to prevent microbial contamination. See section on **ADEQUACY OF PRESERVATION** above.

Investigate what product testing has been performed to determine the type and degree of irritation that may occur when coming into contact with the eye. Examine labels for appropriate warnings and directions for use. Also investigate what antimicrobial testing has been, and is being, carried out to assure that marketed products are not contaminated and will not become contaminated during normal use. Report findings in the EIR.

PERMANENT WAVE NEUTRALIZERS

Permanent wave neutralizers containing either sodium bromate or potassium bromate, can also be purchased in supermarkets, drugstores, and mass merchandise stores. Some beauty supply outlets also sell permanent wave kits labeled "For Professional Use Only" to the general public.

Toxic effects from ingestion of sodium bromate and potassium bromate include nausea and vomiting accompanied by abdominal pain and diarrhea, anemia, destruction of the red blood cells, decreased blood pressure, convulsions, coma, respiratory depression, and possibly death.

In response to documented reports of a number of cases of accidental ingestion by young children of bromate neutralizer solutions, the Consumer Product Safety Commission, under the Poison Prevention Packaging Act of 1970, published a final rule on December 18, 1990, requiring that home permanent wave neutralizers, in liquid form, containing in a single container more than 600 mg. of sodium bromate or more than 50 mg. of potassium bromate be packaged in child-resistant packaging.

Determine if the firm manufactures home permanent wave neutralizers containing sodium bromate or potassium bromate products and if child-resistant packaging is used for such products. Collect samples and report findings in the EIR if child-resistant packaging is not being used.

PRODUCTS CONTAINING ESTROGENIC

HORMONES, PLACENTAL EXTRACT OR

VITAMINS

Products containing estrogen, estrone, estradiol, progesterone, placental extract or vitamins may be considered drugs, misbranded drugs, or misbranded cosmetics, particularly if the label declaration is supplemented with statements implying prevention or treatment of disease or effect on the structure or any function of the human body. See Federal Register Notice of the proposed rule of Oct. 28, 1977 (42 FR 56757) and 21 CFR 201.300.

The estrogen content of an OTC product, be it a drug or a drug as well as cosmetic, may not exceed 10,000 IU per ounce, and users must be directed to limit the amount of product applied daily so that no more than 20,000 IU of estrogen or equivalent be used per month. Some estrogen-containing products have been claiming to prevent or reduce wrinkles, treat seborrhea, or stimulate hair growth. The Advisory Review Panel on OTC Miscellaneous External Drug Products has concluded that there are inadequate data to establish the safety of these products and that they are ineffective and may

therefore be misbranded, even if marketed as cosmetics without making medicinal claims (Advance notice of proposed rulemaking, Federal Register of January 5, 1982, 47 FR 430). In a Final Rule, published in the Federal Register of September 9, 1993, 58 FR 47608, the FDA accepted this panel's recommendation and determined that all topically-applied hormone containing drug products for OTC human use are not generally recognized as safe and effective and are misbranded. In a companion Notice of Proposed Rulemaking published concurrently (58 FR 47611), the Agency proposed to allow as safe the use in cosmetic products of Pregnenolone Acetate up to a level of 0.5% or Progesterone up to a level of 5 mg/oz (product label to specify upper level of consumer usage of finished product containing one of the foregoing substances not to exceed 2 oz per month). The agency also concluded, however, that any use of natural estrogens in cosmetic products makes the product an unapproved new drug. This proposal also designated any cosmetic using the term "hormone" in the text of its labeling or in its ingredient statement as making an implied drug claim, subjecting such a product to regulatory action under Sections 502 and 505 of the Act.

In addition to being considered misbranded drugs, products claiming to contain placental extract may also be deemed to be misbranded cosmetics if the extract has been prepared from placentas from which the hormones and other biologically active substances have been removed and the extracted substance consists principally of protein. The FDA recommends that this substance be identified by a name other than "placental extract" and describing its composition more accurately because consumers associate the name "placental extract" with a therapeutic use of some biological activity.

Cosmetics declaring ingredients as vitamins, as for example, tocopherol as vitamin E, convey the misleading impression that these ingredients and products offer a nutrient or health benefit and may therefore be deemed misbranded. The second edition of the CTFA Cosmetic Ingredient Dictionary, the recognized source of cosmetic ingredient names, lists vitamin ingredients by their respective chemical names.

Review labeling for declaration of estrogenic hormones, placental extract, vitamins and the label statements associated with these ingredients. Report findings in the EIR.

NAIL BUILDERS, HARDENERS, ENAMELS

Nail builders (elongators, extenders) have been involved in numerous reports of irritation, inflammation and infection of the nail bed and nail fold as well as in complaints of discoloration, splitting and loss of fingernails. The products are marketed as kits consisting of a powder (a mixture of methyl methacrylate polymer and peroxide catalyst) and a liquid (a mixture of methacrylate ester monomer and promoter). Ultraviolet light-curing products consist of a single unit containing methacrylate ester monomers, polyurethane and a curing agent (e.g., hydroxycyclohexyl phenyl ketone). The methacrylate monomers currently used in nail builders are mostly ethyl, hydroxy-ethyl, butyl, isobutyl, hydroxypropyl or other esters of methacrylic acid. Methyl methacrylate is now rarely used because a court ruling in an injunction proceeding against a former manufacturer of nail builders and numerous seizures and recalls of methyl methyacrylate containing products. The currently used esters of methacrylic acid may be as harmful as methyl methacrylate.

When a nail builder is manufactured, determine which ester of methacrylic acid is used in the liquid component, review the firm's consumer complaint files, and report findings in the EIR.

Nail hardeners often contain formaldehyde as the active ingredient. Formaldehyde has been reported to be irritating to the skin or cause allergic reactions. In the past, the FDA has not objected to its use as an ingredient of nail hardeners provided the product:

1. Contained no more than 5% formaldehyde.

2. Provided the user with nail shields which restrict application to the nail tip (and not the nail bed or fold).

3. Furnished adequate directions for safe use, and,

4. Warned consumers about the consequences of misuse and potential for causing allergic reactions in sensitized users.

The safety of formaldehyde as a cosmetic ingredient was reviewed in 1984 by a panel of scientific experts appointed by the Cosmetic, Toiletry and Fragrance Association, a trade association representing a major portion of the cosmetic industry. The panel reported that available toxicological data and other information were insufficient to conclude that cosmetics containing formaldehyde in excess of 0.2% are safe. (J. American Coll. Tox., 3,3, 157-184, 1984).

Ascertain the concentration of formaldehyde, inspect the nail shields for proper design and construction. Review labeling for appropriate warnings and directions for use, and review consumer complaint files for the kinds and numbers of adverse reactions associated with this product.

Nail enamels usually consist of nitrocellulose and aryl-sulfonamide-formaldehyde resin as film formers, toluene or ethyl or butyl acetate as solvents, and phthalate, citrate or phosphate esters as plasticizers. Adverse reactions associated with nail enamels are not uncommon. The formaldehyde resin or residual formaldehyde may elicit allergic reactions in already sensitized consumers, the solvents or plasticizers may be irritating, and the deposited film may cause irritation and inflammation because of its occlusiveness or lack of flexibility. Nail enamels marketed as hardeners have had a particularly high rate of adverse reactions. Their high resin content or low concentration of plasticizer causes them to be particularly occlusive and inflexible. Another frequent complaint is flammability during and shortly after application.

ARTIFICIAL OR SCULPTURED FINGERNAIL GLUE

REMOVERS

Household glue removers containing acetonitrile used in removing or debonding glues for artificial or sculptured fingernails may be purchased in supermarkets, drugstores, and mass merchandise stores. Even products labeled "For Professional Use Only" are available for purchase by the general public in retail and "wholesale" beauty supply establishments.

Acetonitrile is toxic by ingestion, inhalation and skin absorption. In response to documented reports of a number of cases of accidental ingestion by young children of sculptured nail removers containing acetonitrile, the Consumer Product Safety Commission, under the Poison Prevention Packaging Act of 1970, published a final rule on December 18, 1990, requiring that household glue removers, in liquid form, containing more than 500 mg. of acetonitrile in a single container be packaged in child-resistant packaging.

Determine if the firm manufactures acetonitrile-containing glue remover products and if child-resistant packaging is used for such products. Collect samples and report findings in the EIR if acetonitrile-containing glue remover products without child-resistant packaging are found.

SOAP

Products that are "soap" are exempt from the provisions of the FD&C Act because soap is excluded from the definition of the term "cosmetic" in Section 201(i) of the Act. The FDA interprets the term "soap" to apply to products:

1. Intended for cleansing the human body,

2. Labeled, sold and represented solely as soap, and,

3. Consisting primarily (i.e., the bulk of its non-violative matter serving as the detergent) of an alkali salt of fatty acids - 21 CFR 701.20.

Products consisting primarily of alkali salts of fatty acids and intended not only for cleansing but for other cosmetic uses, i.e., products intended also for beautifying, promoting attractiveness or altering the appearance, must comply with the regulatory requirements applicable to cosmetics and must, for example, bear ingredient declarations as required at 21 CFR 701.3. They may also be regulated as drugs if intended to cure, treat or prevent disease or to affect the structure or any function of the human body.

Also cosmetics are products not consisting predominantly of alkali salts of fatty acids (i.e., products consisting predominantly of synthetic detergents or combinations of significant proportions of both alkali salts of fatty acids and synthetic detergents) and/or significant levels of other functional additives whose intended purpose in the composition of matter is other than cleansing (i.e., moisturizers, emollients, humectants, anti-irritants, etc.).

Products consisting predominantly of synthetic detergents may be identified in labeling as "soap" if they are intended for cleansing the human body and have the characteristics consumers generally associate with soap.

Products intended solely for cleansing the human body and having characteristics consumers generally associate with soap may be identified in labeling as soap even though they do not consist of detergent ingredients which are predominantly alkali salts of fatty acids. These products are also regulated as cosmetics.

Determine whether the manufactured soap products are cosmetics or are not subject to the provisions of the FD&C Act. Review labeling accordingly for compliance with regulatory requirements.

SUNTAN PRODUCTS

Suntan products generally are sunscreening preparations which, when applied to the skin, permit penetration of sufficient erythemal ultraviolet radiation to produce a perceptible erythema for best tanning results. When used as directed, consumers may remain in the sun for a predetermined time period without risking a sunburn. The sunburn protection is provided by sunscreen active ingredients, e.g., cinoxate, homosalate, padimate o (octyldimethyl PABA).

Suntan products claiming to prevent sunburn are drugs, in addition to being cosmetics. They are also considered drugs if they contain a sunscreen and are represented exclusively for the production of a tan and do not refer in labeling to sunburn protection. See Federal Register notice of proposed rulemaking of August 25, 1978 (43 FR 38206). In the tentative Final Monograph for Sunscreen Drug Products for OTC Human Use, published in the May 12, 1993 Federal Register (58 FR 28194), FDA proposed to regulate all topical products for which tanning claims are made in conjunction with the use of a sunscreen active ingredient inherently as drugs. Exceptions to this, however, were also proposed if the sunscreen ingredient is used in the topical product to achieve a legitimate "qualified cosmetic benefit", such as to protect the integrity of the product formulation's composition of matter (i.e., color, fragrance, or lipids). Such products may be regarded as cosmetics if the term "sunscreen" is not used in label copy, if no SPF value is declared, and if the sunscreen ingredient is disclosed only in the product labeling by its accepted cosmetic name in the cosmetic product ingredient statement

(c.f., 21 CFR 701.3)

For enforcement purposes, the following particulars may serve as a guide for determining whether a product may be treated as a cosmetic or drug or a cosmetic that is also a drug. The product should be regulated as a drug if:

1. The labeling bears any direct or implied statement that the product screens out ultraviolet sunlight, prevents or treats sunburn, helps prevent wrinkles, or prevents premature aging of the skin,

2. The label bears a number representing the sun protection factor (SPF) value, or

3. The sunscreen ingredient is declared as an active drug ingredient and is listed before the listing of the cosmetic ingredients - Section 502(e)(1) of the FD&C Act and 21 CFR 701.3(d).

Products regulated as cosmetics should, and those regulated as drugs must, bear adequate directions for safe use. Section 502(f)(1) of the Act and 21 CFR 201.5. As an example, the labels should state the maximum safe sun exposure period under conditions of prescribed use. Suntan and sunscreen products also must bear warning statements as necessary or appropriate to prevent health hazards - 21 CFR 740.1 and Section 502(f)(2) of the Act. The need for an appropriate warning applies particularly to suntan products not containing a sunscreen ingredient or providing only marginal sunburn protection, such as those with SPF values of less than 4. In the May 12, 1993, Federal Register Notice (see above), FDA proposed to amend the cosmetic regulations to include a new cosmetic warning statement under 21 CFR 740.19, as follows:

Suntanning Preparations. The labeling of suntanning preparations that do not contain a sunscreen ingredient must display the following warning: "Warning-This product does not contain a sunscreen and does not protect against sunburn".

Note that this proposed warning is not yet enacted in final form.

Other "suntan" products of interest are capsules intended for ingestion and containing mostly beta carotene and canthaxanthin. These color additives enter the blood stream and are partially deposited in skin tissue, giving the skin a tan-like color. Neither color additive is approved for this particular use, and products containing them are considered adulterated. Some reports of adverse reactions associated with "tanning pills" have mentioned stomach cramps, hepatitis, nausea, diarrhea, and deposition of the color in the retina of the eye.

In recent years, "suntan accelerators" have appeared on the market. They claim to enhance tanning by stimulating and increasing melanin formation. Because their intended purpose is to affect a function of the human body, they may be considered drugs. One type suntan accelerator is based on bergapten (5-methoxypsoralen) which is found in bergamot oil and is a well-known phototoxic substance, responsible for Berloque Dermatitis. Bergapten increases the skin's sensitivity to ultraviolet light, intensifies erythema formation, and stimulates melanocytes to produce melanin. It has also been reported to be photocarcinogenic in animals. The other kind of suntan accelerator contains tyrosine, alone or in combination with other amino acids, as the "active" principle. Tyrosine is the starting compound of the melanin synthesis in the skin. Its use is based on the assumption that it penetrates the skin, increases tyrosine content of the melanocytes, and thus enhances melanin formation. The effect has not been documented in scientific literature. In fact, an animal study reported a few years ago demonstrated that ingestion or topical application of tyrosine has no effect on melanogensis. The Agency has recently concluded that "suntan accelerators" are unapproved new drugs within the meaning of Section 201(p) of the FD&C Act, and has issued warning letters to several major manufacturers of these products.

Determine whether a manufactured suntan-sunscreen product has been tested for safety as well as for sunscreening effectiveness in accordance with the procedure proposed in the 1978 Federal Register notice (43 FR 38206) and obtain the respective SPF value. Review labels accordingly for appropriate directions for safe use and warnings and for ingredient labeling in compliance with 21 CFR 701.3. Particularly check whether products not containing sunscreen ingredients warn consumers about the risk of sunburn. Inquire about consumer complaints of adverse reactions and lack of sunscreening effectiveness. Report findings on the EIR.

Determine if the firm manufactures and/or distributes tanning products intended for ingestion and containing canthaxanthin, beta carotene or other color additives. Collect samples and report findings to CFSAN with recommendation for regulatory action.

III. INSPECTION

BUILDINGS AND FACILITIES

Determine if the buildings are of suitable size, design and construction and maintained in a clean and orderly manner. Buildings should provide:

1. Adequate space to minimize mixups between different products, raw materials, labeling and cross-contamination.

2. Floors, walls and ceilings constructed of smooth, easily cleanable surfaces.

3. Adequate lighting and ventilation and if necessary for control purposes, screening, filtering, dust, humidity, temperature, and bacteriological controls.

4. Adequate washing, cleaning, plumbing, toilet, and locker facilities, to allow sanitary operation and cleaning of facilities, equipment, and utensils, and to facilitate personal cleanliness.

5. Fixtures, ducts, and pipes installed to prevent condensate or drip contamination in cosmetic materials, utensils, and cosmetic contact surfaces.

EQUIPMENT

Determine if equipment and utensils used in processing, holding, transferring and packaging are of appropriate design, size, material and workmanship to prevent corrosion, accumulation of static material and/or adulteration with lubricants, coolants, dirt, sanitizing agents. The equipment (utensils, transfer piping, cosmetic contact surfaces, etc.) should be:

1. maintained in a clean and orderly manner and sanitized at appropriate times.

2. cleaned and sanitized equipment - stored in a manner that protects it from splash, dust, and other contaminants.

3. constructed to facilitate adjustment, cleaning, and maintenance.

4. of suitable size and accuracy for measuring, mixing, and weighing operations.

PERSONNEL

Determine whether personnel supervising or performing the manufacturing or control of cosmetics have the education, training, and/or expertise to perform their assigned functions.

Observe whether personnel coming in direct contact with cosmetic raw materials, in-process materials, finished products, or contact surfaces wear appropriate outer garments, i.e., uniforms, gloves, hair restraints, etc., maintain adequate personnel cleanliness, are free from abnormal sources of microbiological contamination, i.e., sores, infected wounds, etc.

Determine whether eating food, drinking beverages, or using tobacco is restricted to appropriate designated areas.

RAW MATERIALS

Determine whether raw materials are identified, stored, examined, tested, inventoried, handled, and controlled to assure they conform to appropriate standards. Raw materials should be:

1. stored and handled to prevent mixups, contamination with microorganisms or other chemicals, and degradation from exposure to excessive heat, cold, sunlight, moisture, etc.

2. held in closed containers stored off the floor.

3. maintained in containers that are labeled with the identity, lot number, and control status (release or quarantine).

4. sampled and tested for conformance with specifications and to assure the absence of filth, micro-organisms, and other adulterants. Review animal and vegetable origin materials and those produced by cold processing methods for filth and/or microorganism contamination.

5. properly identified and controlled to prevent the use of materials that fail to meet acceptance specifications.

Determine whether color additives are approved for use in cosmetics (21 CFR 73, 74, & 82) and are certified (21 CFR 74 & 82).

Determine if any cosmetic ingredients are prohibited (21 CFR 700).

PRODUCTION

Determine whether written manufacturing and control procedures have been established, i.e., formulations, processing instructions, in-process control methods, packaging instructions. Evaluate procedures and determine if:

1. the selection, weighing, and measuring of raw materials and the determination of finished yield are reviewed by a second individual.

2. major equipment, transfer lines, containers and tanks used for processing, holding, or filling are identified to indicate contents, batch identification, stage of processing and control status.

3. there are appropriate procedures to prevent contamination with microorganisms or chemicals.

4. there are in-process controls to ensure product uniformity, integrity, i.e., in-process batch weights, fill of mixing containers, adequacy of mixing.

5. the theoretical yield is compared with the actual yield.

LABORATORY CONTROLS

Evaluate laboratory controls including sample collection technique, specifications, test methods, laboratory equipment, and technician qualifications. Determine whether:

1. raw materials, in-process and finished product samples are tested or examined for identity and compliance with applicable specifications, i.e., physical and chemical properties, microbial contamination, and hazards or other chemical contamination.

2. samples are representative of the lot.

3. water used as a cosmetic ingredient is tested regularly for conformance with chemical and micro-biological specifications. See IOM Exhibit 653.1-B for guidance for covering deionized water systems.

4. current finished product production as well as reserve samples are tested for adequacy of preservation against microbial contamination under reasonable conditions of storage and use.

5. reserve samples of approved lots of raw materials and finished products are retained for an adequate time period, i.e., expected shelf-life of the product, one year beyond any expiration date, two years after distribution has been completed, etc., whichever is longer.

6. reserve samples are stored under conditions which protect their integrity, i.e., contamination, deterioration, and are retested at appropriate intervals to assure continued compliance with established specifications.

7. returned cosmetics are examined for deterioration, contamination, and compliance with acceptance specifications.

Determine what toxicological and/or other testing the firm has conducted to substantiate the safety of products. See 21 CFR 740.10.

PACKAGING AND LABELING

Review the immediate and outer container labels and determine if they bear:

1. on the principal display panel:

(a) name of product, statement of identity and net contents. See 21 CFR 701.11 & 13.

(b) if safety of the product has not been substantiated, the statement "Warning - The safety of this product has not been determined". See 21 CFR 740.10.

2. on an appropriate information panel:

(a) name and address of the manufacturer, packer, or distributor. See 21 CFR 701.12.

(b) ingredients listed in descending order of predominance. See 21 CFR 701.3.

(c) warning statements required for self-pressurized containers (21 CFR 740.11), feminine deodorant sprays (21 CFR 740.12), bubble bath products (21 CFR 740.17), and coal tar hair dyes (21 CFR 740.18 and 601(a) of the Act).

(d) any other warning statement necessary or appropriate to prevent a health hazard. See 21 CFR 740.1(a). Identify the health hazard and the basis for the warning statement.

(e) directions for safe use of the product.

Evaluate tamper-resistant packaging and labeling for liquid oral hygiene products and all vaginal products as required by 21 CFR 700.25.

Evaluate primary packaging materials storage and handling procedures for preventing mixups and microbiological or chemical contamination.

Determine whether finished product packages bear meaningful, permanent lot or control numbers. Obtain the key to the coding system.

RECORDS

Review records of origin, receipt, examination, testing, disposition, and use of raw materials to determine adequacy of raw material control.

Determine whether disposition of rejected materials is documented, including any reworking operations.

Evaluate batch production control records and ascertain if they include:

1. documentation of all ingredients (name, code, lot number, quantity, etc.) added to the batch.

2. documentation of all production steps, i.e., processing, handling, transferring, holding, filling.

3. in-process sampling, controlling, and adjusting steps.

4. batch and finished product lot or control numbers.

5. the finished products control status -accepted or rejected.

Evaluate laboratory control records for raw materials, in-process materials, and finished products and include sampling documentation, test results, and interpretation of the test results (accept or reject).

Determine if initial distribution records are retained which identifies the consignee, product, lot or control number.

Determine if records are adequate to conduct an effective recall.

COMPLAINTS

Review complaint files and determine the following:

1. the method for recording, filing, evaluating, and following up both written and verbal complaints.

2. for bodily injury complaints:

(a) the kind and severity of each reported injury.

(b) the body part involved.

(c) product and code numbers.

(d) whether medical treatment by paramedic, primary care physician, or hospital emergency room staff was sought. If it was, determine the nature of the medical treatment and the name of the attending physician or other healthcare professional.

3. the name(s) and location(s) of any poison control center, government agency, physicians group, etc. to whom formula information and/or toxicity data has been provided.

4. the firm's voluntary participation in filing Cosmetic Product Experience Reports (21 CFR 730). Also determine whether the firm utilizes a "screening procedure" on file with FDA for deciding the reportability of adverse reactions. If so, obtain a copy of this screening procedure and attach it to the EIR.

OTHER

Check the firm's voluntary participation in:

1. Registration of Cosmetic

Manufacturing Establishments (21 CFR 710).

2. Cosmetic product ingredient and cosmetic raw material composition statements (21 CFR 720).

IV. SAMPLE COLLECTION

COMPLIANCE SAMPLES

General - Collect compliance samples if adulteration or misbranding is noted or suspected, or on special assignment, including follow-up to a cosmetic-related adverse reaction.

Obtain the key to code at the time of sampling (or from file at district office) and explain in C/R under "remarks."

Collect the following quantities (these include quantities for 702(b) samples) and ship for testing as indicated below.

Chemical Analysis - Collect at least three units and not less than 340 gm (12 oz) total quantity in duplicate and ship to the office of Cosmetics and Colors, Division of Programs and Enforcement Policy (HFS-105), except for:

Collect in Duplicate

Aerosol products 680 gm (24 oz)

Bath Salts 680 gm (24 oz)

Bubble Baths 680 gm (24 oz)

Eye Make-ups 56 gm (2 oz)

Facial Make-ups 225 gm (8 oz)

Mouthwashes 680 gm (24 oz)

Nail preparations 160 gm (6 oz)

Perfumes 160 gm (6 oz)

Pressed Powders 160 gm (6 oz)

Microbiological analysis and filth examination - Collect at least ten individual retail units [20 units if less than 14 gm (1/2 oz) each] or 1-100 gm (4 oz) subsamples from each of ten containers of bulk material and ship to the microbiological laboratory which normally services your district. Collect subs in duplicate.

Nits in natural bristle brushes - Examine at least six brushes in each lot. Collect samples for district laboratory examination if nit infestation is observed in two or more brushes; or if only one out of six brushes bears ten or more infested bristles. Collect a minimum of six brushes for laboratory confirmation.

Color Analysis - Collect at least three units and not less than 225 gm (8 oz) total quantity in duplicate and ship to the regional color analyst.

Toxicity Testing - On assignment or clearance by the Office of Cosmetics and Colors, Division of Programs and Enforcement (HFS-105), collect at least three units and not less than 160 gm (6 oz) total quantity and ship to the Office of Cosmetics and Colors, Division of Programs and Enforcement (HFS-105) for testing.