

*What Every Member of the
Trade Community Should Know About:*

Beauty and Skin Care Products of Heading 3304



AN INFORMED COMPLIANCE PUBLICATION
JULY 2006

U.S. CUSTOMS and BORDER PROTECTION

NOTICE:

This publication is intended to provide guidance and information to the trade community. It reflects the position on or interpretation of the applicable laws or regulations by U.S. Customs and Border Protection (CBP) as of the date of publication, which is shown on the front cover. It does not in any way replace or supersede those laws or regulations. Only the latest official version of the laws or regulations is authoritative.

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PREFACE

On December 8, 1993, Title VI of the North American Free Trade Agreement Implementation Act (Pub. L. 103-182, 107 Stat. 2057), also known as the Customs Modernization or “Mod” Act, became effective. These provisions amended many sections of the Tariff Act of 1930 and related laws.

Two new concepts that emerge from the Mod Act are “***informed compliance***” and “***shared responsibility***”, which are premised on the idea that in order to maximize voluntary compliance with laws and regulations of U.S. Customs and Border Protection, the trade community needs to be clearly and completely informed of its legal obligations. Accordingly, the Mod Act imposes a greater obligation on CBP to provide the public with improved information concerning the trade community’s rights and responsibilities under customs regulations and related laws. In addition, both the trade and U.S. Customs and Border Protection share responsibility for carrying out these requirements. For example, under Section 484 of the Tariff Act, as amended (19 U.S.C. 1484), the importer of record is responsible for using reasonable care to enter, classify and determine the value of imported merchandise and to provide any other information necessary to enable U.S. Customs and Border Protection to properly assess duties, collect accurate statistics, and determine whether other applicable legal requirements, if any, have been met. CBP is then responsible for fixing the final classification and value of the merchandise. An importer of record’s failure to exercise reasonable care could delay release of the merchandise and, in some cases, could result in the imposition of penalties.

The Office of Regulations and Rulings (ORR) has been given a major role in meeting the informed compliance responsibilities of U.S. Customs and Border Protection. In order to provide information to the public, CBP has issued a series of informed compliance publications on new or revised requirements, regulations or procedures, and a variety of classification and valuation issues.

This publication, prepared by the National Commodity Specialist Division, ORR, pertains to the classification of the beauty and skin care products of heading 3304, HTSUS. We sincerely hope that this material, together with seminars and increased access to rulings of U.S. Customs and Border Protection, will help the trade community to improve voluntary compliance with customs laws and to understand the relevant administrative processes.

The material in this publication is provided for general information purposes only. Because many complicated factors can be involved in customs issues, an importer may wish to obtain a ruling under Regulations of U.S. Customs and Border Protection, 19 C.F.R. Part 177, or to obtain advice from an expert who specializes in customs matters, for example, a licensed customs broker, attorney or consultant.

Comments and suggestions are welcomed and should be addressed to the Assistant Commissioner at the Office of Regulations and Rulings, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, (Mint Annex) NW, Washington, D.C. 20229.

Sandra L. Bell,
Acting Assistant Commissioner
Office of Regulations and Rulings

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INTRODUCTION

Chapter 33 pertains to the classification of ESSENTIAL OILS AND RESINOIDS; PERFUMERY, COSMETIC OR TOILET PREPARATIONS. This informed compliance report will focus on the classification of the beauty and skin care products of heading 3304, HTSUS. The multi-billion dollar beauty and skin care industry, formerly focused exclusively on women's beauty and skin care products, has evolved into an industry, which markets preparations for babies, children, teenagers, and men. Heading 3304, HTSUS, provides for:

Beauty or make-up preparations and preparations for the care of the skin (other than medicaments), including sunscreen or sun tan preparations; manicure or pedicure preparations.

3304.10 - Lip make-up preparations

3304.20 - Eye make-up preparations

3304.30 - Manicure or pedicure preparations

Other :

3304.91 - Powders, whether or not compressed

3304.99 -- Other

LAW AND CLASSIFICATION

Proper classification of merchandise entering the territory of the United States is the responsibility of the importing public pursuant to the Customs Modernization Act. U.S. Customs and Border Protection enforces the laws and regulations.

Classification of merchandise under the Harmonized Tariff Schedule of the United States (HTSUS) is in accordance with the General Rules of Interpretation (GRI's). GRI 1 provides that classification shall be determined according to the terms of the headings and any relative section or chapter notes. The chapter notes provide legal guidance to the proper classification of the merchandise within the headings and subheadings. The *Harmonized Commodity Description and Coding System Explanatory Notes* (referred to as E.N. or *Explanatory Notes*) constitute the official interpretation of the Harmonized System at the international level. While neither legally binding nor dispositive, the Explanatory Notes provide a commentary on the scope of each heading of the Harmonized System and are generally indicative of the proper interpretation of these headings. See T.D. 89-80, 54 FR 35127, 35128 (August 23, 1989).

DEFINITIONS

Heading 3304 encompasses make-up, cosmetic, beauty, and skin care products used to enhance and provide care for the lips, eyes, face, and body. We note that the

Harmonized Tariff Schedule and the Explanatory Notes do not define the terms beauty preparations, make-up preparations, or cosmetics. Tariff terms are construed in accordance with their common and commercial meaning. *Nippon Kogasku (USA), Inc. v. United States*, 69 CCPA 89, 673 F.2d 380 (1982). Common and commercial meaning may be determined by consulting dictionaries, lexicons, scientific authorities and other reliable sources. *C.J. Tower & Sons v. United States*, 69 CCPA 128, 673 F.2d 1268 (1982).

MAKE-UP

Make-up is defined in Merriam-Webster Online Dictionary as:

- (1) *Cosmetics used to color and beautify the face*
- (2) *A cosmetic applied to other parts of the body*

COSMETIC

The Encyclopedia Britannica (Online) defines the term **cosmetic** as:

Any of several preparations (excluding soap) that are applied to the human body for beautifying, preserving, or altering the appearance or for cleansing, coloring, conditioning, or protecting the skin, hair, nails, lips, eyes, or teeth.

PREPARATION

The term **preparation** is not defined in the Harmonized Tariff Schedule. Customs ruling HQ 965977 dated December 19, 2002, addresses the term **preparation**. The relevant definition of **preparation** found in the Oxford English Dictionary, 2281 (compact ed. 1987), is:

A substance specially prepared, or made up for its appropriate use or application, e.g. as food or medicine, or in the arts or sciences.

Webster's Third New International Dictionary, 1790 (unabridged 1986), states:

Something that is prepared: something made, equipped, or compounded for a specific purpose.

In the Random House Unabridged Dictionary (2d ed. 1993) **preparation** is, in pertinent part:

Something prepared, manufactured or compounded: a special preparation for sunbathers.

Each definition states that a **cosmetic, make-up, or preparation** is made for a specific purpose. As the terms of heading 3304, HTSUS, provide for beauty, make-up and skin care preparations; goods of the heading must consist of preparations made for these specific purposes. Lipstick, foundation, blush, eye shadow, and skin care lotions are some of the exemplars listed in the Explanatory Notes to heading 3304, HTSUS. These preparations are for the care or beautification of the skin or other external features.

MAKE-UP PREPARATIONS

Make-up or cosmetic preparations are used to beautify or enhance the eyes, lips, nails, or face. The preparations include eye make-up, lip make-up, and facial make-up, which are provided for in subheadings 3304.10, 3304.20, 3304.30, 3304.91, and 3304.99, HTSUS. Theatrical make-up, grease paints, and Halloween make-up are also classifiable in heading 3304 HTSUS. Make-up preparations manufactured and marketed for children and teenagers are classifiable in heading 3304, HTSUS, provided they contain all the necessary ingredients to be marketed as make-up preparations. Make-up preparations of subheadings 3304.10 through 3304.99 pertain to products imported in retail packages or in bulk. Information on bulk make-up preparations is discussed in the section on RETAIL AND BULK PREPARATIONS.

SUBHEADING 3304.10.0000, HTSUS - LIP MAKE-UP PREPARATIONS

Subheading 3304.10.0000, HTSUS, provides for make-up preparations for the lips. Lipstick, in stick, tube, cream or palette, is classifiable in this provision, as well as lip-gloss, lip pencil, lip crayon, lip liner, lip plumper, non-medicated lip balm, theatrical lip make-up preparations, and lip make-up preparations used for Halloween.

EXCLUSIONS

Medicated lip preparations for the treatment of cold sores and other medical conditions of the lips are excluded from subheading 3304.10.0000, HTSUS. Medicated lip preparations are classifiable in Chapter 30.

SUBHEADING 3304.20.0000, HTSUS - EYE MAKE-UP PREPARATIONS

Subheading 3304.20.0000, HTSUS, provides for preparations for the beauty of the eye area. Eye make-up preparations classifiable in 3304.20.0000, HTSUS, include mascara, eye shadow (powder, cream, liquid), eyebrow products (pencils, gel, powder), eyeliners (liquid, pencils, cream and powder), theatrical eye make-up, Halloween eye make-up, and other make-up preparations for the eye area.

EXCLUSIONS

Fashion contact lenses used to color or enhance the eyes are not classifiable as cosmetics or eye make-up preparations in subheading 3304.20.0000, HTSUS. The fashion contact lenses are classifiable in subheading 9001.30.00, HTSUS (HQ 966568).

Eyelash curlers, eye make-up brushes, applicators, and other eye make-up tools and implements are excluded from classification in subheading 3304.20.0000, HTSUS, and classifiable in the Chapter appropriate to the individual item.

SUBHEADING 3304.30.0000, HTSUS - MANICURE AND PEDICURE PREPARATIONS

Manicure and pedicure preparations are provided for in subheading 3304.30.0000, HTSUS. As noted above, **preparations** are mixtures, compounds, or other substances. The Explanatory Notes to heading 3304 (B) Manicure or Pedicure Preparations provides that “*This part covers nail polishes, nail varnishes, nail varnish removers, cuticle removers and other preparations for use in manicure or pedicure.*” The products classifiable in subheading 3304.30.0000, HTSUS, include preparations used for the care and beautification of the hands and feet. Products in this subheading include, but are not limited to: nail polish, nail varnish, nail enamel, basecoats, undercoats, cuticle softeners, cuticle remover, nail strengthening products, nail extenders, nail polish, nail varnish and enamel removers.

Hand soaks and foot soaks, which may contain ingredients similar to bath salts, are classifiable as manicure or pedicure preparations of subheading 3304.30.0000, HTSUS, and not as bath salts of subheading 3307.30.1000, HTSUS (HQ 964333). The products may consist of small tablets, which are intended to be dissolved in a sink or small basin filled with water so that fingernails, toenails, cuticles and feet will be softened to facilitate grooming during a manicure or pedicure. Although the ingredient composition of the hand and foot soaks is similar to that of bath preparations, because of the relatively small size, the articles have no other practical use than as manicure preparations. When dissolved, the tablets will form a solution that will be an integral part of the manicure process.

EXCLUSIONS

Wadding, felt, or nonwovens impregnated with nail polish remover are excluded from classification in subheading 3304.30.0000, HTSUS, as a *Manicure or pedicure preparation*. These products fall in subheading 3307.90.0000, HTSUS. For further information, please refer to the section on PAPERS IMPREGNATED OR COATED WITH COSMETICS; WADDING, FELT AND NONWOVENS IMPREGNATED, COATED OR COVERED WITH PERFUME OR COSMETICS.

Implements or tools such as emery boards, cuticle sticks, nail clippers, nail buffers or abrasive articles are not preparations, and therefore, are not classifiable as manicure or pedicure preparations in subheading 3304.30.0000, HTSUS. Manicure and pedicure tool sets are classifiable in subheading 8214.20, HTSUS, which provides for *Manicure and pedicure sets, and combinations thereof, in leather cases or other containers of types ordinarily sold therewith in retail sales*. Individual manicure and pedicure tools are classifiable in the appropriate Chapter for the tool or implement.

Artificial fingernails, excluded from subheading 3304.30.0000, HTSUS, are classified in subheading 3926.40, HTSUS.

Products used in the care of animal claws are classifiable in subheading 3307.90.0000, HTSUS.

OTHER BEAUTY, MAKE-UP OR SKIN CARE PREPARATIONS SUBHEADINGS 3304.91- 3304.99, HTSUS

Explanatory Notes to heading 3304, HTS provide:

This part covers (3) Other beauty or make-up preparations and preparations for the care of the skin (other than medicaments), such as: face powders (whether or not compressed), baby powders (including talcum powder, not mixed, not perfumed, put up for retail sale), other powders and grease paints; beauty creams, cold creams, make-up creams, cleansing creams, skin food (including those containing bees' royal jelly) and skin tonics or body lotions; petroleum jelly put up in packing of a kind sold by retail for the care of the skin; barrier creams to give protection against skin irritants injectable intracutaneous gels for wrinkle elimination and lip enhancement (including those containing hyaluronic acid); anti-acne preparations (other than those of heading 3401) which are designed primarily to cleanse the skin and which do not contain sufficiently high levels of active ingredients to be regarded as having primary therapeutic or prophylactic effect against acne; toilet vinegars which are mixtures of vinegars or acetic acid and perfumed alcohol. Sunscreen or suntan preparations are also included.

Make-up and beauty care preparations not enumerated in subheadings 3304.10, HTSUS, through 3304.30, HTSUS, are classifiable in subheadings 3304.91, HTSUS, through 3304.99, HTSUS. These subheadings include preparations used in the regimen of beauty and care of the face and body, such as cold creams, foundations, powders, lotions, and sunscreen preparations.

SUBHEADING 3304.91.00, HTSUS - POWDERS, WHETHER OR NOT COMPRESSED

Subheading 3304.91.00, HTSUS provides for *Powders, whether or not compressed*, used for body and facial care. Baby powders, talcum powder and dusting powder, whether or not perfumed, are classified in subheading 3304.91.0050, HTSUS. Rouges, whether or not compressed, are classifiable in subheading 3304.91.0010, HTSUS. Compressed facial and foundation powders, as well as loose facial and foundation powders, are classifiable in this subheading. All other powders, whether or not compressed, such as concealers, blushes, color correctors, and highlighters, among others, are classified in subheading 3304.91.00, HTSUS.

EXCLUSIONS

Eye shadow in powder form is classifiable in subheading 3304.20.0000, HTSUS, which provides for *Eye make-up preparations*.

Bulk talc, not perfumed nor formulated for use as talcum powder, is excluded from classification in subheading 3304.91.00, HTSUS and classifiable in subheading 2526.20.00, HTSUS, which provides for *Talc, crushed or powdered*.

OTHER BEAUTY, MAKE-UP PREPARATIONS, AND SKIN CARE PREPARATIONS - SUBHEADING 3304.99, HTSUS

Subheading 3304.99, HTSUS, provides for all other beauty, make-up, and skin care preparations not outlined in the previous subheadings:

- 1) Petroleum jelly in retail packages,
- 2) Suntan and sunscreen preparations,
- 3) Beauty, make-up, and cosmetic preparations,
- 4) Skin care preparations.

PETROLEUM JELLY IN RETAIL PACKAGES - SUBHEADING 3304.99.1000, HTSUS

Petroleum jelly, put up in retail packages and labeled for skin care use, is classifiable in subheading 3304.99.1000, HTSUS.

Petroleum jelly, other than that suitable for the care of the skin, put up in packing of a kind sold by retail for such use, is not classifiable in subheading 3304.99.1000, HTSUS; rather it is classifiable in heading 2712, HTSUS.

SUNTAN AND SUNSCREEN PREPARATIONS - SUBHEADING 3304.99.5000, HTSUS

Suntan and sunscreen preparations are classifiable in subheading 3304.99.5000, HTSUS. Suntan preparations are utilized to promote a tan, whereas sunscreen preparations contain substances to protect the skin against UVB rays. Products classifiable in this provision include: suntan gels, suntan creams, suntan oils, suntan liquids, self-tanners, skin gels for accelerating, enhancing or extending tans, sunscreen oils, sunscreen liquids, sunscreen gels and sunscreen creams.

EXCLUSIONS

Suntan and sunscreen pads, nonwovens, and towelettes are excluded from classification in subheading 3304.99.5000, HTSUS, and are classifiable in subheading 3307.90.0000, HTSUS. For further information please refer to the section on PAPERS IMPREGNATED OR COATED WITH COSMETICS; WADDING, FELT AND NONWOVENS IMPREGNATED, COATED OR COVERED WITH PERFUME OR COSMETICS.

BEAUTY, MAKE-UP, and COSMETIC PREPARATIONS - SUBHEADING 3304.99.5000, HTSUS

Cosmetics, make-up, and beauty care products other than lip make-up preparations, eye make-up preparations, manicure preparations, and pedicure preparations, and powders, whether or not compressed, are classifiable in subheading 3304.99.5000, HTSUS. This subheading includes makeup and beauty preparations for the beautification of the face and skin not enumerated in subheadings 3304.10 through 3304.30. Beauty, make-up or cosmetic preparations which are covered under this provision are: blush (liquid, gel and cream), rouge (liquid, cream and gel), facial foundation (liquid, cream and stick), leg and body paints, make-up bases, make-up fixatives, facial and body concealers, color correctors (cream and liquid), skin highlighters, body concealers, and other beauty, make-up, and cosmetic preparations.

SKIN CARE PREPARATIONS - SUBHEADING 3304.99.5000, HTSUS

Skin care preparations for the care of the face and body, including preparations containing subsidiary pharmaceutical constituents, are classifiable in subheading 3304.99.5000, HTSUS. The preparations classifiable in this provision cover products designed for the skin care of babies, children, teenagers, men, and women. Skin care preparations classifiable in this subheading include but are not limited to: cold creams, facial toner, facial and skin astringents, beauty creams, moisturizing creams and lotions, night creams and lotions, non-medicated face and body skin lightener creams and lotions, facial tonics, barrier creams and skin protective preparations, facial and body skin masks, facial fresheners, facial and body exfoliants, skin toners, skin clarifiers,

body scrubs, skin abrasive preparations, facial clarifiers, skin cream, and creams for cellulite reduction. Baby skin care products include baby lotions, baby oils, and baby skin care creams.

EXCLUSIONS

Skin care cleansing products containing surfactants are excluded from classification in Chapter 33. Heading 3401.30, HTSUS, provides for *Organic surface-active products and preparations for washing the skin, in the form of liquid or cream and put up for retail sale, whether or not containing soap.*

Facial, hand, body, and baby wipes containing surfactants are excluded from Chapter 33 and are classifiable in Chapter 34.

Antiperspirants, personal deodorants, depilatories, and shaving preparations are classifiable in heading 3307, HTSUS.

SUBSIDIARY PHARMACEUTICAL CONSTITUENTS

As per the Explanatory Notes to Chapter 33, preparations for the care of the skin that contain subsidiary constituents are classifiable in heading 3304.

The products of headings 33.03 to 33.07 remain in these headings whether or not they contain subsidiary pharmaceutical or disinfectant constituents, or are held out as having subsidiary therapeutic or prophylactic value (see Note 1 (d) to Chapter 30).

However, medical preparations having a subsidiary use as cosmetic preparations are excluded from heading 3304, and are classified in Chapter 30. Acne preparations, such as acne lotions, gels, and creams, which contain subsidiary pharmaceutical constituents, would be classifiable in subheading 3304.99.5000, HTSUS. The Explanatory Notes to heading 3304 state that *anti-acne preparations (other than soaps of heading 34.01) which are designed primarily to cleanse the skin and which do not contain sufficiently high levels of active ingredients to be regarded as having a primary therapeutic or prophylactic effect against acne* remain in heading 3304, HTSUS.

Injectable intracutaneous gels for wrinkle elimination and lip enhancement, such as products containing hyaluronic acid, are classifiable in subheading 3304.99.5000, HTSUS. Over-the-counter skin care preparations marketed for the elimination of the appearance of wrinkles which contain retinol, alpha hydroxy acids or beta hydroxy acids are classifiable in subheading 3304.99.5000, HTSUS, provided the pharmaceutical ingredients are subsidiary constituents.

PAPERS IMPREGNATED OR COATED WITH COSMETICS; WADDING, FELT AND NONWOVENS IMPREGNATED, COATED OR COVERED WITH PERFUME OR COSMETICS

Beauty, make-up and skin care preparations are manufactured and marketed in many forms – bottles, jars, pumps, boxes, pads and towelettes. Chapter 33 Note 4 states:

The expression “perfumery, cosmetic or toilet preparations” in heading No. 33.07 applies, inter alia, to the following products: scented sachets, odoriferous preparations which operate by burning; perfumed papers and papers impregnated, coated or covered with perfume or cosmetics.

Beauty, make-up or skin care preparations manufactured in the form of impregnated papers, wadding, felt and nonwovens are classified in heading 3307 rather than in heading 3304 as per Chapter 33 Note 4 (HQ 966959, HQ 955960). Nail polish remover pads are classifiable in subheading 3307.90.0000, HTSUS. Papers impregnated with facial powder are classifiable in subheading 3307.90.0000, HTSUS, rather than as powders of subheading heading 3304.91.00, HTSUS. Suntan towelettes are classifiable in subheading 3307.90.0000, HTSUS and not in subheading 3304.99.5000, HTSUS.

RETAIL AND BULK PREPARATIONS

Heading 3304 provides for numerous beauty and skin care products. These products may be imported in retail packages or in bulk containers. Beauty, make-up, cosmetic or skin care preparations in retail packages must be labeled for such and conform to the labeling requirements as set forth by the Food and Drug Administration in the Federal Food, Drug and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA), which will be discussed later in this publication. Chapter 33 Note 3 states that:

Headings 33.03 to 33.07 apply, inter alia, to products, whether or not mixed (other than aqueous distillates and aqueous solutions of essential oils), suitable for use as goods of these headings and put up in packings of a kind sold by retail for such use.

The Explanatory Notes to headings 3303 - 3307 state:

Preparations (e.g., varnish) and unmixed products (e.g., unperfumed powdered talc, fuller’s earth, acetone, alum) which are suitable for other uses in addition to those described above are classified in these headings only when they are (a) In packings of a kind sold to the consumer and put up with labels, literature or other indications that they are for use as perfumery, cosmetic or toilet preparations, or as room deodorisers; (b) Put up in a form clearly specialised to such use (e.g., nail varnish put up in small bottles furnished with the brush required for applying the varnish).

Beauty, make-up or skin care preparations, which contain a single component and are imported in retail packages with labels or literature to indicate the use as beauty, make-up or skin care preparations, are classifiable in heading 3304, HTSUS. Acetone, packaged and labeled in retail bottles, which is marketed as a nail polish remover, is classifiable in subheading 3304.30.0000, HTSUS, which provides for *Manicure or pedicure preparations*. Acetone, imported in bulk, i.e. packed in drums or containers, is classifiable as a separately chemically defined chemical compound of subheading 2914.11, HTSUS, which provides for *Acetone*. Similarly, talc, when put up in packages to be sold at retail, with all appropriate labels for use as a skin care preparation, would be classifiable in 3304.91.00, HTSUS. Bulk talc is classifiable in Chapter 25.

Beauty, make-up, cosmetic and skin care formulations, when imported in bulk containers to be later packaged for retail sale in the United States, are classifiable in heading 3304, HTSUS, provided the formulations contain all necessary ingredients for the specified use (HQ 965857, HQ 965977). Bulk lipstick mass, consisting of all necessary ingredients ready to be molded into lipstick, will be classified in subheading 3304.10.0000, HTSUS, which provides for *Lip make-up preparations*. The bulk lipstick mass must contain all the essential ingredients at the time of importation, i.e., coloring ingredients, wax, fragrance, etc., as the finished product to be sold at retail. Lipstick mass that does not contain essential components of lipstick such as coloring matter would be classified in heading 3824, HTSUS.

FOOD AND DRUG ADMINISTRATION LAWS

Cosmetics marketed in the United States must be in compliance with the provisions of the Federal Food, Drug and Cosmetic Act (FD&C Act), the Fair Packaging and Labeling Act (FPLA), and the regulations published under the authority of these laws. The Food and Drug Administration (FDA) works closely with US Customs and Border Protection to monitor imports. Under section 801(a) of the FD&C act, cosmetics being imported or offered for import into the United States are subject to review by the FDA. Violative products must be brought into compliance (if feasible). Products that are not or cannot be brought into compliance will be refused admission by FDA. Once refused, these products must be exported or destroyed.

COSMETIC LABELING

The cosmetics distributed in the United States must comply with the labeling regulations published by the FDA under the authority of the FD&C Act and the FPLA. Labeling means all labels and other written, printed or graphic matter on or accompanying a product. The label statements required under the authority of the FD&C Act must appear on the inside as well as any outside container or wrapper. FPLA requirements, e.g., ingredient labeling and statement of the net quantity of contents on the principal display panel, only apply to the label of the outer container. The labeling requirements are codified at 21 CFR 701 and 740. Cosmetics bearing false or misleading label

statements or otherwise not labeled in accordance with these requirements may be considered misbranded and may be subject to regulatory action.

The principal display panel, i.e., the part of the label most likely displayed or examined under customary conditions of display for sale (21 CFR 701.10), must state the name of the product, identify by descriptive name or illustration the nature or use of the product, and bear an accurate statement of the net quantity of contents of the cosmetic in the package in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The declaration must be distinct, placed in the bottom area of the panel in line generally parallel to the base on which the package rests, and in a type size commensurate with the size of the container as prescribed by regulation. The net quantity of contents statement of a solid, semisolid or viscous cosmetic must be in terms of the avoirdupois pound and ounce, and a statement of liquid measure must be in terms of the U.S. gallon of 231 cubic inches and the quart, pint, and fluid ounce subdivisions thereof. If the net quantity of contents is one pound or one pint or more, it must be expressed in ounces, followed in parenthesis () by a declaration of the largest whole units (i.e., pounds and ounces or quarts and pints and ounces). The net quantity of contents may additionally be stated in terms of the metric system of weight or measures.

The name and place of business of the firm marketing the product must be stated on an information panel of the label (21 CFR 701.12). The address must state the street address, city, state, and zip code. If a firm is listed in a current city or telephone directory, the street address may be omitted. If the distributor is not the manufacturer or packer, this fact must be stated on the label by the qualifying phrase "Manufactured for..." or "Distributed by..." or similar, appropriate wording.

The Tariff Act of 1930 requires that all imported articles state on the label the English name of the country of origin.

DECLARATION OF INGREDIENTS

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

(21 CFR 701.3(p)). Off-package ingredient labeling is permitted if the cosmetic is held in tightly compartmented trays or racks, not enclosed in a folding carton, and the package surface area is less than 12 square inches (21 CFR 701.3(i)).

The ingredients must be declared in descending order of predominance. Color additives (21 CFR 701.3(f)(3)) and ingredients present at one percent or less (21 CFR 701.3(f)(2)) may be declared without regard for predominance. The ingredients must be identified by the names established or adopted by regulation (21 CFR 701.3(c)); those accepted by the FDA as exempt from public disclosure may be stated as "and other ingredients" (21 CFR 701.3(a)).

Cosmetics which are also drugs must first identify the drug ingredient(s) as "active ingredient(s)" before listing the cosmetic ingredients (21 CFR 701.3(d)).

All label statements required by regulation must be in the English language and must be placed on the label or labeling with such prominence and conspicuousness that they are readily noticed and understood by consumers under customary conditions of purchase (21 CFR 701.2).

ADDITIONAL INFORMATION

The Internet

The home page of U.S. Customs and Border Protection on the Internet's World Wide Web, provides the trade community with current, relevant information regarding CBP operations and items of special interest. The site posts information -- which includes proposed regulations, news releases, publications and notices, etc. -- that can be searched, read on-line, printed or downloaded to your personal computer. The web site was established as a trade-friendly mechanism to assist the importing and exporting community. The web site also links to the home pages of many other agencies whose importing or exporting regulations that U.S. Customs and Border Protection helps to enforce. The web site also contains a wealth of information of interest to a broader public than the trade community. For instance, on June 20, 2001, CBP launched the "Know Before You Go" publication and traveler awareness campaign designed to help educate international travelers.

The web address of U.S. Customs and Border Protection is <http://www.cbp.gov>

Customs Regulations

The current edition of *Customs Regulations of the United States* is a loose-leaf, subscription publication available from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; telephone (202) 512-1800. A bound, 2003 edition of Title 19, *Code of Federal Regulations*, which incorporates all changes to the Regulations as of April 1, 2003, is also available for sale from the same address. All proposed and final regulations are published in the *Federal Register*, which is published daily by the Office of the Federal Register, National Archives and Records Administration, and distributed by the Superintendent of Documents. Information about on-line access to the *Federal Register* may be obtained by calling (202) 512-1530 between 7 a.m. and 5 p.m. Eastern time. These notices are also published in the weekly *Customs Bulletin* described below.

Customs Bulletin

The *Customs Bulletin and Decisions* ("Customs Bulletin") is a weekly publication that contains decisions, rulings, regulatory proposals, notices and other information of interest to the trade community. It also contains decisions issued by the U.S. Court of International Trade, as well as customs-related decisions of the U.S. Court of Appeals for the Federal Circuit. Each year, the Government Printing Office publishes bound volumes of the *Customs Bulletin*. Subscriptions may be purchased from the Superintendent of Documents at the address and phone number listed above.

Importing Into the United States

This publication provides an overview of the importing process and contains general information about import requirements. The February 2002 edition of *Importing Into the United States* contains much new and revised material brought about pursuant to the Customs Modernization Act ("Mod Act"). The Mod Act has fundamentally altered the relationship between importers and U.S. Customs and Border Protection by shifting to the importer the legal responsibility for declaring the value, classification, and rate of duty applicable to entered merchandise.

The February 2002 edition contains a section entitled "Informed Compliance." A key component of informed compliance is the shared responsibility between U.S. Customs and Border Protection and the import community, wherein CBP communicates its requirements to the importer, and the importer, in turn, uses reasonable care to assure that CBP is provided accurate and timely data pertaining to his or her importation.

Single copies may be obtained from local offices of U.S. Customs and Border Protection, or from the Office of Public Affairs, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW, Washington, DC 20229. An on-line version is available at the CBP web site. *Importing Into the United States* is also available for sale, in single copies or bulk orders, from the Superintendent of Documents by calling (202) 512-1800, or by mail from the Superintendent of Documents, Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-7054.

Informed Compliance Publications

U.S. Customs and Border Protection has prepared a number of Informed Compliance publications in the "*What Every Member of the Trade Community Should Know About...*" series. Check the Internet web site <http://www.cbp.gov> for current publications.

Value Publications

Customs Valuation under the Trade Agreements Act of 1979 is a 96-page book containing a detailed narrative description of the customs valuation system, the customs valuation title of the Trade Agreements Act (§402 of the Tariff Act of 1930, as amended by the Trade Agreements Act of 1979 (19 U.S.C. §1401a)), the Statement of Administrative Action which was sent to the U.S. Congress in conjunction with the TAA, regulations (19 C.F.R. §§152.000-152.108) implementing the valuation system (a few sections of the regulations have been amended subsequent to the publication of the book) and questions and answers concerning the valuation system. A copy may be obtained from U.S. Customs and Border Protection, Office of Regulations and Rulings, Value Branch, 1300 Pennsylvania Avenue, (Mint Annex) NW, Washington, D.C. 20229.

Customs Valuation Encyclopedia (with updates) is comprised of relevant statutory provisions, CBP Regulations implementing the statute, portions of the Customs Valuation Code, judicial precedent, and administrative rulings involving application of valuation law. A copy may be purchased for a nominal charge from the Superintendent of Documents, Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15250-7054. This publication is also available on the Internet web site of U.S. Customs and Border Protection.

The information provided in this publication is for general information purposes only. Recognizing that many complicated factors may be involved in customs issues, an importer may wish to obtain a ruling under CBP Regulations, 19 C.F.R. Part 177, or obtain advice from an expert (such as a licensed Customs Broker, attorney or consultant) who specializes in customs matters. Reliance solely on the general information in this pamphlet may not be considered reasonable care.

Additional information may also be obtained from U.S. Customs and Border Protection ports of entry. Please consult your telephone directory for an office near you. The listing will be found under U.S. Government, Department of Homeland Security.

“Your Comments are Important”

The Small Business and Regulatory Enforcement Ombudsman and 10 regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement activities and rate each agency’s responsiveness to small business. If you wish to comment on the enforcement actions of U.S. Customs and Border Protection, call 1-888-REG-FAIR (1-888-734-3247).

REPORT SMUGGLING 1-800-BE-ALERT OR 1-800-NO-DROGA



Visit our Internet web site: <http://www.cbp.gov>