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COSMETIC REGISTRATION

SUBCHAPTER D—COSMETICS

PART 170—VOLUNTARY REGISTRATION OF COSMETIC PRODUCT ESTABLISHMENTS

PART 172—VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT AND COSMETIC RAW MATERIAL COMPOSITION STATEMENTS

In the matter of issuing regulations establishing a procedure for (1) the voluntary registration of cosmetic product establishments and (2) the voluntary filing of cosmetic product ingredient statements:

A notice regarding these regulations which were based on two petitions filed by the Cosmetic, Toiletry, and Fragrance Association, Inc. (CTFA), 1625 I Street NW, Washington, DC 20006, was published in the FEDERAL REGISTER of August 26, 1971 (36 F.R. 16934). In the same notice the Commissioner of Food and Drugs proposed a parenthetical statement which, if the regulations were adopted, would be inserted to identify certain cosmetic products that are also regarded as drugs by the Food and Drug Administration. Interested persons were invited to submit comments on the proposal within a 30-day period which ended September 25, 1971. Twenty-two comments were received.

With regard to the promulgation of these regulations in general, a member of Congress urged that the registration and filing of ingredient statements by producers of cosmetics be mandatory, that foreign producers of cosmetics be subjected to the regulations, and that ingredient labeling of cosmetic products be required. Two other comments challenged the legality of establishing voluntary regulations under section 701(a) of the Federal Food, Drug, and Cosmetic Act and urged that the regulations issued be mandatory. These two comments included legal arguments to support claims that it is extra legal to provide that data submitted voluntarily by firms filing cosmetic product ingredient statements be kept confidential by FDA; that authority now exists to require mandatory registration of cosmetic product establishments, filing of cosmetic ingredient statements, label declaration of ingredients on cosmetic products, and label declaration of any registration number issued by the Commissioner; and that authority now exists to provide that any cosmetic product that did not have an FDA-issued registration number on the label would be deemed to be misbranded.

The Commissioner has considered these comments and concludes that under section 701(a) of the act he is authorized to accept the voluntary registration of cosmetic product establishments and the voluntary filing of cosmetic product ingredient statements and cosmetic raw material composition statements as set forth in the regulations established below. He also agrees that foreign producers should be included in this voluntary registration. He concludes however that promulgation of a mandatory regulation could result in lengthy litigation that would seriously delay FDA from obtaining the type of information expected as result of this promulgation. If it is determined that the information obtained through the procedure established in these regulations does not adequately contribute to the efficient enforcement of the act, additional steps will be taken to promulgate mandatory regulations. The Commissioner further concludes that mandatory ingredient labeling goes beyond the scope of the proposal and cannot be implemented by these regulations.

Comments recommending label declarations of ingredients for cosmetic products are considered by the Commissioner to be meritorious. The Commissioner recognizes that regulations requiring cosmetic product ingredient disclosure on the labels of such products will prevent the deception of consumers and facilitate value comparisons. This issue was not a part of the CTFA petitions. Consideration is being given to publishing a proposal under the Federal Fair Packaging and Labeling Act, section 5(c)(3), 15 U.S.C. 1454(c)(3), for labeling of sensitizing ingredients.

A dermatologist commented that the proposed regulations were a step in the right direction but that they did not go far enough, particularly in the provision for providing coded samples to physicians treating persons suffering from allergic reaction. He urged establishment of a "Register" that would list all ingredients of all cosmetic products used in the United States and would be made available to every practicing dermatologist. The Commissioner concludes that a "Register" of cosmetic ingredients goes beyond the scope of the proposal and cannot be implemented by these regulations. The Commissioner considers that promulgation of labeling requirements for cosmetic ingredients will substantially satisfy the need of dermatologists for this type of data.

One comment from a professor at a school of medicine urged that feminine hygiene deodorants be considered drugs as are feminine douche products. This request was also included in the comment submitted by the member of Congress. Twelve of those commenting opposed the Commissioner's proposed parenthetical statement. These comments have been fully considered.

The Commissioner concludes that the parenthetical statement is not a necessary element of this voluntary regulation. In lieu of this statement, the proposed regulations have been changed to indicate that a cosmetic product which is also a drug is subject to the drug requirements of the Federal Food, Drug, and Cosmetic Act.

In his proposed parenthetical statement, the Commissioner cited cosmetic product categories which are also regarded as drugs because of their intended use. He would like to point out that the failure to cite feminine hygiene deodorants as an example should not be construed to indicate that such products may not also be considered drugs under appropriate circumstances.

One comment concerned the possible theft of ingredient information and urged that funds commensurate with the value of the formulations submitted to FDA be set aside to reimburse the owner of a stolen cosmetic formulation. The Commissioner concludes that creation of a special fund goes beyond the scope of the proposal and cannot be implemented by these regulations.

A public interest group objected to the all-inclusive scope of the petitioner's proposed provisions concerning confidentiality of statements submitted pursuant to Part 172. The commissioner concludes that these objections are valid, and the regulations have been changed so that such provisions are consistent with the mandate of section (3)(e)(4) of the Administrative Procedures Act (5 U.S.C. 552(b)(4)).

Fourteen associations or firms that are either involved in or closely allied to the cosmetic product industry favored the regulations proposed by the petitioner. However, some of these suggested amendatory language that would clarify and improve the procedure for obtaining compositional information regarding proprietary ingredients used in finished cosmetics.

Accordingly, on the basis of the comments received and the Commissioner's conclusions, the proposed regulations are being promulgated with the following changes:

1. For clarity, the titles of Parts 170 and 172 have been changed and new definitions are added to §§ 171.1 and 172.1.

2. Changes have been made throughout Parts 170 and 172 in order to include foreign cosmetic producers in these voluntary registration procedures.

3. A sentence has been added to § 172.1 (b) to point out that a cosmetic product which is also a drug is subject to the drug provisions of the act.

4. Clarifying changes have been made in § 172.5(a)(1) and (2), (b)(5), (d)(2) and (3), and (e), and a new subdivision has been added to paragraph (d)(1).

5. A new § 172.6 *Information requested about cosmetic* raw material has been added, and proposed §§ 172.6–172.9 have been redesignated as §§ 172.7–172.10.

6. To further implement new § 172.6, appropriate amendments have been made in §§ 172.2, 172.3, 172.4, 172.7 and 172.9.

7. The section heading of § 172.8 has been changed and the section is revised to clarify the procedure for acknowledging the receipt of statements, advising persons filing incomplete statements, and issuing statement numbers to persons filing complete statements.

8. Section 172.9 is revised to clarify the conditions under which trade secrets, and other privileged and confidential commercial information will be held in confidence consistent with the provisions of section 3(e)(4) of the Administrative Procedures Act as amended.

9. A new paragraph (b) has been added to § 172.10 to explain how the Food and Drug Administration Cosmetic Raw Material Composition Statement Number may be used.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 601, 602, 701(a), 704, 52 Stat. 1054 as amended, 1055, 1057 as amended; 21 U.S.C. 361, 362, 371(a), 374) and under authority delegated to the Commissioner (21 CFR 2.120): *It is ordered*, That 21 CFR Chapter I be editorially amended by redesignating the present Subchapters D and E as Subchapters E and F, respectively, and that a new Subchapter D—Cosmetics be established consisting at this time of two new Parts 170 and 172, as follows:

Sec.
170.1 Definitions.
170.2 Who should register.
170.3 Time for registration.
170.4 How and where to register.
170.5 Information requested.
170.6 Amendments to registration.
170.7 Notification of registrant; cosmetic products establishment registration number.
170.8 Inspection of registrations.
170.9 Misbranding by reference to registration or to registration number.
170.51 Exemptions.

AUTHORITY: The provisions of this Part 170 issued under secs. 601, 602, 701(a), 704, 52 Stat. 1054, as amended, 1055, 1057, as amended; 21 U.S.C. 361, 362, 371(a), 374.

§ 170.1 Definitions.

(a) The term "cosmetic product" means a finished cosmetic the manufacture of which has been completed.

(b) "Establishment" means a place of business where cosmetic products are manufactured or packaged.

(c) The term "manufacture" of a cosmetic product means the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product.

(d) The term "packaging" of a cosmetic product means filling or labeling the product container, including changing the immediate container or label (but excluding changing other labeling) at any point in the distribution of the cosmetic product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer.

(e) The term "all business trading names used by the establishment" means any name which is used on a cosmetic product label and owned by the cosmetic product manufacturer or packer, but is different from the principal name under which the cosmetic product manufacturer or packer is registered.

(f) The term "act" means the Federal Food, Drug, and Cosmetic Act.

(g) The definitions and interpretations contained in sections 201 and 602 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in the regulations in this part.

§ 170.2 Who should register.

The owner or operator of a cosmetic product establishment which is not exempt under § 170.51 and engages in the manufacture or packaging of a cosmetic product is requested to register for each such establishment, whether or not the product enters interstate commerce. This request extends to any foreign cosmetic product establishment whose products are exported for sale in any State as defined in section 201(a)(1) of the act. No registration fee is required.

§ 170.3 Time for registration.

The owner or operator of an establishment entering into the manufacture or packaging of a cosmetic product should register his establishment within 30 days after the operation begins.

§ 170.4 How and where to register.

FD Form 2511 ("Registration of Cosmetic Product Establishment") is obtainable on request from the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C. 20204, or at any Food and Drug Administration district office. The completed form should be mailed to Cosmetic Product Establishment Registration, Food and Drug Administration,

Department of Health, Education, and Welfare, Washington, D.C. 20204.

§ 170.5 Information requested.

FD Form 2511 requests information on the name and address of the cosmetic product establishment, including post office ZIP code; all business trading names used by the establishment; the kind of ownership or operation (e.g., individually owned, partnership, or corporation); and the type of business (manufacturer, packer, and/or distributor). The information requested should be given separately for each establishment as defined in § 170.1(b).

§ 170.6 Amendments to registration.

Within 30 days after a change in any of the information contained on a submitted FD Form 2511, a new FD Form 2511 should be submitted to amend the registration. This amendment is also necessary when a registration is to be canceled because an establishment has changed its name and no longer conducts business under the original name.

§ 170.7 Notification of registrant; cosmetic product establishment registration number.

The Commissioner of Food and Drugs will provide the registrant with a validated copy of FD Form 2511 as evidence of registration. This validated copy will be sent only to the location shown for the registering establishment. A permanent registration number will be assigned to each cosmetic product establishment registered in accordance with the regulations in this part.

§ 170.8 Inspection of registrations.

A copy of the FD Form 2511 filed by the registrant will be available for inspection at the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C. 20204.

§ 170.9 Misbranding by reference to registration or to registration number.

Registration of a cosmetic product establishment or assignment of a registration number does not in any way denote approval of the firm or its products by the Food and Drug Administration. Any representation in labeling or advertising that creates an impression of official approval because of registration or possession of a registration number will be considered misleading.

§ 170.51 Exemptions.

The following classes of persons are not requested to register in accordance with this Part 170 because the Commissioner has found that such registration is not justified:

(a) Beauty shops, cosmetologists, retailers, pharmacies, and other persons and organizations that compound cosmetic products at a single location and administer, dispense, or distribute them at retail from that location and who do not otherwise manufacture or package cosmetic products at that location.

(b) Physicians, hospitals, clinics, and public health agencies.

(c) Persons who manufacture, prepare, compound, or process cosmetic products solely for use in research, pilot plant production, teaching, or chemical analysis, and who do not sell these products.

(d) Carriers, by reason of their receipt, carriage, holding, or delivery of cosmetic products in the usual course of business.

Sec.

AUTHORITY: The provisions of this Part 172 issued under secs. 601, 602, 701(a), 704, 52 Stat. 1054, as amended, 1055, 1057, as amended; 21 U.S.C. 361, 362, 371(a), 374.

§ 172.1 Definitions.

(a) The term "commercial distribution" of a cosmetic product means annual gross sales in excess of $1,000 for that product.

(b) The term "cosmetic product" means a finished cosmetic the manufacture of which has been completed. Any cosmetic product which is also a drug or device or component thereof is also subject to the requirements of Chapter V of the act.

(c) The term "flavor" means any natural or synthetic substance or substances used solely to impart a taste to a cosmetic product.

(d) The term "fragrance" means any natural or synthetic substance or substances used solely to impart an odor to a cosmetic product.

(e) The term "ingredient" means any single chemical entity or mixture used as a component in the manufacture of a cosmetic product.

(f) The term "proprietary ingredient" means any cosmetic product ingredient whose name, composition, or manufacturing process is protected from competition by secrecy, patent, or copyright.

(g) The term "chemical description" means a concise definition of the chemical composition using standard chemical nomenclature so that the chemical structure or structures of the components of the ingredient would be clear to a practicing chemist. When the composition cannot be described chemically, the substance shall be described in terms of its source and processing.

(h) The term "cosmetic raw material" means any ingredient, including an ingredient that is a mixture, which is used in the manufacture of a cosmetic product for commercial distribution and is supplied to a cosmetic product manufacturer, packer, or distributor by a cosmetic raw material manufacturer or supplier.

(i) The definitions and interpretations contained in sections 201, 601, and 602 of the act shall be applicable to such terms when used in the regulations in this part.

§ 172.2 Who should file.

(a) Either the manufacturer, packer, or distributor of a cosmetic product is requested to file FD Form 2512 ("Cosmetic Product Ingredient Statement") whether or not the cosmetic product enters interstate commerce. This request extends to any foreign manufacturer, packer, or distributor of a cosmetic product exported for sale in any State as defined in section 201(a)(1) of the act. No filing fee is required.

(b) It is requested that FD Form 2513 ("Cosmetic Raw Material Composition Statement") be filed by either the manufacturer or supplier of a cosmetic raw material that is a proprietary ingredient or whose precise composition is not known to the cosmetic manufacturer, packer, or distributor receiving the ingredient whether or not the raw material enters into interstate commerce. This request extends to any foreign manufacturer or supplier of a cosmetic raw material that is exported for such use in any State as defined in section 201(a)(1) of the act. No filing fee is required.

§ 172.3 Times for filing.

(a) Within 180 days after forms are made available to the industry, FD Form 2512 should be filed for each cosmetic product being commercially distributed as of the effective date of this part. FD Form 2512 should be filed within 60 days after the beginning of commercial distribution of any product not covered within the 180-day period.

(b) FD Form 2513 should be filed, pursuant to § 172.2(b), by a cosmetic raw material manufacturer or supplier for each cosmetic raw material.

§ 172.4 How and where to file.

FD Form 2512 and FD Form 2513 and FD Form 2514 ("Discontinuance of Commercial Distribution of Cosmetic Product or Cosmetic Raw Material") are obtainable on request from the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C. 20204, or at any Food and Drug Administration district office. The completed form should be mailed or delivered to: Cosmetic Product Statement, Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D.C. 20204, according to the instructions provided with the forms.

§ 172.5 Information requested about cosmetic products.

(a) FD Form 2512 requests information on:

(1) The name and address, including post office ZIP code, of the person (manufacturer, packer, or distributor) designated on the label of the product.

(2) The name and address, including post office ZIP code, of the manufacturer or packer of the product if different from the person designated on the label of the product, when the manufacturer or

packer submits the information requested under this paragraph.

(3) The brand name or names of the cosmetic product.

(4) The cosmetic product category or categories.

(5) The ingredients in the product.

(b) The person filing FD Form 2512 should:

(1) Provide the information requested in paragraph (a) of this section.

(2) Have the form signed by an authorized individual.

(3) Provide poison control centers with ingredient information and/or adequate diagnostic and therapeutic procedures to permit rapid evaluation and treatment of accidental ingestion or other accidental use of the cosmetic product.

(4) Provide ingredient information (and, when requested, ingredient samples) to a licensed physician who, in connection with the treatment of a patient, requests assistance in determining whether an ingredient in the cosmetic product is the cause of the problem for which the patient is being treated.

(5) Request that an FD Form 2513 be filed pursuant to § 172.6(b) by the manufacturer or supplier of any proprietary ingredient (including mixtures) or of any other cosmetic raw material which is used as an ingredient and has not as yet been assigned a cosmetic raw material composition statement number.

(c) One or more of the following cosmetic product categories should be cited to indicate the product's intended use.

(1) *Baby products.* (i) Baby shampoos.

(ii) Lotions, oils, powders, and creams.

(iii) Other baby products.

(2) *Bath preparations.* (i) Bath oils, tablets, and salts.

(ii) Bubble baths.

(iii) Bath capsules.

(iv) Other bath preparations.

(3) *Eye makeup preparations.* (i) Eyebrow pencil.

(ii) Eyeliner.

(iii) Eye shadow.

(iv) Eye lotion.

(v) Eye makeup remover.

(vi) Mascara.

(vii) Other eye makeup preparations.

(4) *Fragrance preparations.* (i) Colognes and toilet waters.

(ii) Perfumes.

(iii) Powders (dusting and talcum) (excluding aftershave talc).

(iv) Sachets.

(v) Other fragrance preparations.

(5) *Hair preparations (noncoloring).* (i) Hair conditioners.

(ii) Hair sprays (aerosol fixatives).

(iii) Hair straighteners.

(iv) Permanent waves.

(v) Rinses (noncoloring).

(vi) Shampoos (noncoloring).

(vii) Tonics, dressings, and other hair grooming aids.

(viii) Wave sets.

(ix) Other hair preparations.

(6) *Hair coloring preparations.* (i) Hair dyes and colors (all types requiring caution statement and patch test).

(ii) Hair tints.

(iii) Hair rinses (coloring).

(iv) Hair shampoos (coloring).

(v) Hair color sprays (aerosol).

(vi) Hair lighteners with color.

(vii) Hair bleaches.

(viii) Other hair coloring preparations.

(7) *Makeup preparations (not eye).* (i) Blushers (all types).

(ii) Face powders.

(iii) Foundations.

(iv) Leg and body paints.

(v) Lipstick.

(vi) Makeup bases.

(vii) Rouges.

(viii) Makeup fixatives.

(ix) Other makeup preparations.

(8) *Manicuring preparations.* (i) Basecoats and undercoats.

(ii) Cuticle softeners.

(iii) Nail creams and lotions.

(iv) Nail extenders.

(v) Nail polish and enamel.

(vi) Nail polish and enamel removers.

(vii) Other manicuring preparations.

(9) *Oral hygiene products.* (i) Dentifrices (aerosol, liquid, pastes, and powders).

(ii) Mouthwashes and breath fresheners (liquids and sprays).

(iii) Other oral hygiene products.

(10) *Personal cleanliness.* (i) Bath soaps and detergents.

(ii) Deodorants (underarm).

(iii) Douches.

(iv) Feminine hygiene deodorants.

(v) Other personal cleanliness products.

(11) *Shaving preparations.* (i) Aftershave lotions.

(ii) Beard softeners.

(iii) Men's talcum.

(iv) Preshave lotions (all types).

(v) Shaving cream (aerosol, brushless, and lather).

(vi) Shaving soap (cakes, sticks, etc.).

(vii) Other shaving preparation products.

(12) *Skin care preparations (creams, lotions, powder, and sprays).* (i) Cleansing (cold creams, cleansing lotions, liquids, and pads).

(ii) Depilatories.

(iii) Face, body, and hand (excluding shaving preparations).

(iv) Foot powders and sprays.

(v) Hormone.

(vi) Moisturizing.

(vii) Night.

(viii) Paste marks (mud packs).

(ix) Skin lighteners.

(x) Skin fresheners.

(xi) Wrinkle smoothing (removers).

(xii) Other skin care preparations.

(13) *Suntan and sunscreen preparations.* (i) Suntan gels, creams, and liquids.

(ii) Indoor tanning preparations.

(iii) Other suntan preparations.

(d) Ingredients in the product should be indicated as follows:

(1) A list of each ingredient of the cosmetic product in descending order of predominance by weight (except that the fragrance and/or flavor may be designated as such without naming each individual ingredient when the manufacturer or supplier of the fragrance and/or flavor refuses to disclose ingredient data) should be accompanied by a letter designating the percentage of the ingredient added, as follows:

(i) The letter A represents over 50 percent.

(ii) The letter B represents over 25 percent to 50 percent.

(iii) The letter C represents over 10 percent to 25 percent.

(iv) The letter D represents over 5 percent to 10 percent.

(v) The letter E represents over 1 percent to 5 percent.

(vi) The letter F represents over 0.1 percent to 1 percent.

(vii) The letter G represents 0.1 percent or less.

(viii) The letter H represents 0 percent. (The letter H is to be used only to indicate that a particular color additive is absent in certain shades of a product as described in the instructions in FD Form 2512.)

(2) An ingredient, including an ingredient that is a mixture, should be listed by its common or usual name, if it has one; or by its chemical name (except proprietary ingredients); or by its trade name and the name of manufacturer or supplier. If such ingredient complies with a published standard (e.g., "The United States Pharmacopeia," "National Formulary," "Food Chemicals Codex," "CTFA Standards—Specifications," etc.) list only the common, usual, or chemical name found in the published standard and the name of the standard used. If a cosmetic raw material composition statement number has already been assigned to an ingredient, list only the number and the name under which the ingredient was registered.

(3) When the manufacturer or supplier of a fragrance and/or flavor refuses to disclose ingredient data, the fragrance and/or flavor should be listed as such with the product name and/or trade name or number and the name of the manufacturer or supplier of each proprietary mixture that is included.

(e) A separate FD Form 2512 should be filed for each different formulation of a cosmetic product. However, except for the hair coloring preparations listed in paragraph (c)(6) of this section for which a statement for each shade of such product is required, a single FD Form 2512 may be filed for two or more shades of a cosmetic product where only the amounts of the color additive ingredient used are varied or in the case of flavors and fragrances where only the amounts of the flavors and fragrances used are varied.

§ 172.6 Information requested about cosmetic raw materials.

(a) FD Form 2513 requests information on:

(1) The name and address, including post office ZIP code, of the manufacturer or supplier of the cosmetic raw material.

(2) The trade name or names of the cosmetic raw material.

(3) The identity of the ingredient in a cosmetic raw material or of the ingredi-

ents if the cosmetic raw material is a mixture.

(b) The person filing FD Form 2513 should:

(1) Provide the information requested in paragraph (a) of this section for each cosmetic raw material which is to be an ingredient in a cosmetic product offered for commercial distribution, whenever it is a proprietary ingredient (except that the fragrance and/or flavor may be designated as such without naming each individual ingredient when the manufacturer or supplier of the fragrance and/or flavor refuses to disclose ingredient data) or an ingredient whose precise composition is not known to the cosmetic product manufacturer, packer, or distributor using it.

(2) Have it signed by an authorized individual.

(c) Information on the composition of cosmetic raw material should be shown as follows:

(1) A cosmetic raw material or an ingredient in a cosmetic raw material, including mixtures, should be listed by its common or usual name, if it has one; or its chemical name; or its chemical description. If this information is not available, list the trade name and supplier and request the manufacturer or supplier to file an FD Form 2513. If such cosmetic raw material or ingredient complies with a published standard (e.g. "The United States Pharmacopeia," "National Formulary," "Food Chemicals Codex," "CTFA Standards—Specifications," etc.) list only the common, usual, or chemical name in the published standard and the name of the standard used. If a cosmetic raw material composition statement number has already been assigned to an ingredient, list only the number and the name under which the ingredient was registered.

(2) A cosmetic raw material that is a prepared mixture of ingredients should have each ingredient listed in descending order of predominance by weight (except that fragrance and/or flavor, if present, may be designated as such without naming each individual ingredient when the manufacturer or supplier of the fragrance and/or flavor refuses to disclose ingredient data) with a letter designating the percentage of the ingredient added as described under § 172.5(d)(1).

(3) When the manufacturer or supplier of a fragrance and/or flavor refuses to disclose ingredient data, the fragrance and/or flavor used in a cosmetic raw material should be listed as such with the product name and/or trade name or number and the name of the manufacturer or supplier.

(4) Ingredients in a prepared mixture of color additives, with or without diluents, that are used as cosmetic raw materials should be listed as described in subparagraphs (1) and (2) of this paragraph, using the approved FDA name of the color additive and/or diluent as listed in Part 8 of this chapter.

(d) The information requested should be given separately for each cosmetic raw material.

§ 172.7 Amendments to statement.

(a) Changes in the information requested under § 172.5(a) (3) and (5) on the ingredients or brand name of a cosmetic product should be submitted by filing an amended FD Form 2512, within 60 days after the product is entered into commercial distribution. Other changes do not justify immediate amendment, but should be shown by filing an amended FD Form 2512 within a year after such changes. Notice of discontinuance of commercial distribution of a cosmetic product should be submitted by FD Form 2514 within 180 days after discontinuance of commercial distribution becomes known to the person filing.

(b) Changes in the information requested under § 172.6(a) (2) and (3) on the name or ingredients of a cosmetic raw material should be submitted by filing an amended FD Form 2513 on or before the time the cosmetic raw material is supplied to a cosmetic product manufacturer, packer, or distributor for use in a product for commercial distribution. The manufacturer, packer, or distributor should also be informed about any change in the name of a cosmetic raw material so he can send an amended FD Form 2512 as requested in paragraph (a) of this section. Other changes should be indicated by filing an amended FD Form 2513 within a year after these changes are made. Notice of discontinuance of commercial distribution of a cosmetic raw material should be submitted by FD Form 2514 within 180 days after discontinuance of commercial distribution becomes known to the person filing.

§ 172.8 Notification of person submitting cosmetic product ingredient statement and cosmetic raw material composition statement.

When FD Forms 2512 and 2513 are received, the Commissioner of Food and Drugs will either assign a permanent cosmetic statement number or an FDA reference number in those cases where a permanent number cannot be assigned. Receipt of the forms will be acknowledged by sending the individual signing the statement an appropriate notice bearing either the FDA reference number or the permanent cosmetic statement number. If the person submitting FD Form 2512 has not complied with § 172.5(b)(1) and (2) or the person submitting FD Forms 2513 has not complied with § 172.6(b), he will be notified as to the manner in which his statement is incomplete.

§ 172.9 Confidentiality of statements.

(a) Each item of information contained in, attached to, or included with FD Forms 2512, 2513, 2514, and amendments thereto and constituting a trade secret or other privileged and confidential commercial information exempt from disclosure to the public must be clearly marked as confidential. Each item of information so marked must be accompanied by a statement setting forth adequate grounds to justify its confidentiality. If the Food and Drug Administration concludes that an item so marked is not exempt from disclosure to the public, the person submitting the information will be informed and will be given an opportunity to appeal that decision to the Assistant Commissioner for Public Affairs, whose decision on the matter will be final.

(b) Data and information otherwise exempt from public disclosure may be revealed in administrative or court enforcement proceedings where the data or information are relevant. Any such use will be in a manner that reduces public disclosure to the minimum necessary under the circumstances.

(c) Data and information otherwise exempt from public disclosure may be disclosed to consultants, advisory committees, and other persons who are special government employees. Such persons are thereafter subject to the same restrictions with respect to disclosure as any Food and Drug Administration employee.

§ 172.10 Misbranding by reference to filing or to statement number.

(a) The filing of an FD Form 2512 or 2513 or assignment of a number to the statement does not in any way denote approval by the Food and Drug Administration of the firm or the product. Any representation in labeling or advertising that creates an impression of official approval because of such filing or such number will be considered misleading, except as set forth in paragraph (b) of this section.

(b) The manufacturer or supplier of a cosmetic raw material that has been assigned a Food and Drug Administration Cosmetic Raw Material Composition Statement number (FDA CRMCS No.) pursuant to § 172.8 may use this number without violating the misbranding provision of this section under the following conditions:

(1) The FDA CRMCS No. is placed on the label of the container which is used to ship or transport the cosmetic raw material to a manufacturing establishment if the principal display panel of the label also contains the following disclaimer: ["The FDA Cosmetic Raw Material Composition Statement number is assigned for raw material identification purposes only and does not in any way denote approval of the firm or the raw material by the Food and Drug Administration."] The disclaimer phrase shall be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices) as to render it likely to be read and understood by the ordinary individual.

(2) The FDA CRMCS No. is used in cosmetic raw material trade literature, catalogue citations, and correspondence if the disclaimer specified in subparagraph (1) of this paragraph is made on the same page that the FDA CRMCS No. appears.

Effective date. Part 170 shall become effective 30 days after notice that FD Form 2511 is available for distribution, and Part 172

days after notice that FD Forms 2512, 2513, and 2514 are available for distribution. Notice of the date each of the forms will be available will be published in the FEDERAL REGISTER. It is anticipated that FD Form 2511 will be available on a date to be announced during April 1972 and that FD Forms 2512, 2513, and 2514 will be available on a date to be announced in May 1972. In the meantime, those desiring any of these forms may submit requests to the Food and Drug Administration as set forth in §§ 170.4 and 172.14 (21 CFR 170.4 and 172.4).

Dated: March 31, 1972.

CHARLES C. EDWARDS,
Commissioner of Food and Drugs.

[FR Doc.72-5208 Filed 4-6-72;8:45 am]