

The cosmetic, toiletry, and fragrance industry, frequently referred to simply as the cosmetic industry, produces personal care products that are considered everyday essentials. What follows serves as a brief introduction to translating technical material for this field. It covers common terminology and provides definitions, resources, and reference materials. Although the author translates from French into English, the information presented here will be useful for any translator working in the cosmetic field.

Areas of Interest

For the technical translator, the most important areas of the cosmetic industry are:

- Laboratory and manufacturing processes (e.g., batch records, formulation, standard operating procedures, packaging).
- Patents and regulatory affairs (e.g., labeling, litigation).
- Science (e.g., skin, hair, aging; emulsions, surfactants, dyes).

Typical texts for technical translators could deal with the following:

- A justification for the use of a certain active ingredient in a sunscreen, its formulation, and protective effect on the skin.
- Manufacturing procedures for producing lipsticks on an industrial scale, then packaging them.

- A patent application for a hair permanent, complete with equations and chemical formulae.
- A label and insert for an anti-aging moisturizer that must comply with rules governing the nature of the terms and claims used.

Industry Resources

The following are important industry associations whose websites are generally excellent sources of wide-ranging background information:

Personal Care Products Council

www.personalcarecouncil.org (Formerly the Cosmetic, Toiletry, and Fragrance Association)

European Cosmetics Association www.colipa.com

Food and Drug Administration Center for Food Safety and Applied Nutrition

www.cfsan.fda.gov

La Fédération des Industries de la Parfumerie

www.fipar.com (This site contains links to other related French organizations.)

Society of Cosmetic Chemists www.scconline.org

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Soap and Detergent Association www.cleaning101.com

Japan Cosmetic Industry Association

www.jcia.org

Other useful industry sites include:

Translators need to understand the differences in the ways cosmetics, drugs, and soap are regulated in order to grasp the context in which their documents are framed.

SpecialChem Cosmetics

www.specialchem4cosmetics.com (Contains information on formulation and ingredients.)

CosmeticsDesign

www.cosmeticsdesign.com (This is a source for business news on cosmetics formulation and packaging in North America.)

HBA Global Expo Annual Health and Beauty America Trade Fair

www.hbaexpo.com (This is the place to go to find information on the largest product development event and education conference for the personal care,

fragrance, wellness, and cosmetic

industry.)

Ouid.fr

www.quid.fr/selection.html?catid= 17&subcatid=527

(This site has links to many of the world's large cosmetic companies, with flags showing the languages of each website)

Defining Cosmetics, Drugs, and Soap

There are differences in the ways cosmetics, drugs, and soap are regulated. Translators working in the cosmetic industry need to understand these differences in order to grasp the context in which their documents are framed.

Cosmetics

In the U.S., the Food, Drug, and Cosmetic Act [FD&C Act, sec. 201(i)] defines cosmetics as:

"Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance."

It is this *intended use* that is important, and products that have two intended uses are classified as both drugs *and* cosmetics. A shampoo is a cosmetic because its intended use is to cleanse the hair. An antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug. Other examples include fluoride toothpaste, deodorants that are also antiperspirants, and moisturizers and makeup marketed with sun protection claims.

Over-the-counter Drugs

Many products that are commonly referred to as cosmetics or toiletries are in fact over-the-counter (OTC)

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drugs, that is, drugs sold without a prescription. The Food and Drug Administration (FDA) website, and particularly the Center for Drug Evaluation and Research (CDER), provides a detailed explanation of the criteria and process for marketing OTC drugs. Some relevant links for these types of drugs from the FDA and CDER include:

FDA Center for Drug and Evaluation and Research Office of Nonprescription Products

www.fda.gov/cder/offices/otc/default.htm

FDA Frequently Asked Questions on the Regulatory Process of OTC Drugs

www.fda.gov/cder/about/smallbiz/ OTC_FAQ.htm

FDA Center for Devices and Radiological Health

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm? FR=201.66

(This site contains information on labeling.)

In this area, it is important to understand monographs, which specify active ingredients for OTC drugs. Monographs are different from new drug applications (NDAs), which are required for prescription drugs. The CDER explains the distinction as follows:

"Legal marketing is in compliance with an OTC drug monograph. Unlike NDAs, which are based on drug products, monographs specify the active ingredients that can be contained within OTC drug products. An OTC drug products. An OTC drug product containing ingredients that comply with standards established in an applicable monograph is consid-

ered to be 'generally recognized as safe and effective' (GRASE), and does not require specific FDA approval before marketing. For example, OTC sunscreen drug products can be legally marketed if they contain ingredients which comply with the standards estab-

lished in the OTC sunscreen monograph for formulation, labeling, and testing."²

Soap

Soap is a special case. Not every product marketed as soap meets the official definition of the term. The

Navigating the Cosmetic Industry

EU Cosmetics Directive

ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm

U.S. Food and Drug Administration

www.cfsan.fda.gov/~dms/cos-218.html

Japan's Pharmaceutical Affairs Law

www5.cao.go.jp/otodb/english/houseido/hou/lh 02070.html

Comparison of FDA and EU Regulations from the Consumer's Point of View

www.pgbeautyscience.com/ u.s.-and-eu-cosmetic-regulation-similarities.html

Cosmetic Ingredient Review

www.cir-safety.org

Cosmetics & Toiletries

www.cosmeticsandtoiletries.com

The Beauty Brains

www.thebeautybrains.com

(A humorous blog: cosmetic scientists answer readers' questions.)

FDA interprets the term "soap" to apply only when:

"The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the product's detergent properties are due to the alkali-fatty acid compounds," and "the product is labeled, sold, and represented solely as soap."

Regulatory Bodies

The three most important markets for the cosmetic industry are the European Union (EU), the U.S., and Japan. Although there are moves to standardize regulations worldwide-Japan, in particular, used to have substantially different rules from the EU and the FDA—fundamental differences still remain in terms of permitted efficacy and marketing claims, as well as ingredients on the positive list (the list of permitted ingredients). As a result, familiarity with the statutes and regulatory bodies governing these key markets can be very useful for translators practicing in the cosmetic field.

In Japan, the cosmetic industry is governed by the Pharmaceutical Affairs Law (www5.cao.go.jp/otodb/english/houseido/hou/lh_02070.html). The U.S. cosmetic industry is regulated by the FDA, relevant links for

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which were provided earlier in this article. In the EU, the important resource is the Cosmetics Directive, which can be found in 19 languages at ec.europa.eu/enterprise/cosmetics/html/consolidated_dir.htm. The "Annexes" included at this site are very useful. This website also contains a very informative table comparing FDA and EU regulations from the consumer's point of view (visit www.pgbeautyscience.com/u.s.-and-eu-cosmetic-regulation-similarities.html).

Know the Industry

Familiarity with basic product categories, key markets, and regulatory environments is important in understanding the worldwide cosmetic industry. Translators will find these core concepts very useful as a basis for tackling the more detailed technical problems common to translation for the cosmetic industry.

Notes

- 1. U.S. Food, Drug, and Cosmetic Act, sec. 201(i)
 - www.fda.gov/opacom/laws/fdcact/ fdcact1.htm
- 2. FDA Center for Drug Evaluation and Research, Regulatory Mechanisms for Marketing OTC Drug Products
 - www.fda.gov/Cder/Offices/OTC/reg_mechanisms.htm
- 3. FDA Center for Drug Evaluation and Research, Center for Food Safety and Applied Nutrition [21 CFR 701.20]

http://vm.cfsan.fda.gov/~dms/cos-218.html

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