

[YOUR COMPANY LETTERHEAD]

I, [NAME OF COMPANY REPRESENTATIVE], being duly sworn, depose and say: I am [TITLE] for [COMPANY] a corporation organized and existing under the laws of the State of [NAME OF STATE], United States of America.

[COMPANY NAME] with a manufacturing facility at [ADDRESS], is lawfully engaged in the business of manufacturing various cosmetic products, which are listed in the attachment/or listed below:

Replace the previous statement with the following if products are manufactured for a distributor:

[COMPANY NAME] with a manufacturing facility at [ADDRESS], is lawfully engaged in the business of manufacturing various cosmetic products for [NAME OF DISTRIBUTOR], located at [DISTRIBUTOR'S ADDRESS], which are listed below.

[LIST OF PRODUCTS]

[COMPANY NAME] manufactures its products in compliance with all local and state laws and regulations and the Federal Food, Drug and Cosmetic Act, and [COMPANY NAME] products are permitted to be sold in interstate commerce throughout the United States.

Replace the previous statement with the following if products are manufactured by a contract manufacturer:

[COMPANY NAME] has its products manufactured by contract manufacturers, [NAME OF CONTRACT MANUFACTURER AND ADDRESS]. [COMPANY NAME - not contract manufacturers name] products are manufactured in compliance with all local and state laws and regulations and the Federal Food, Drug and Cosmetic Act, and [COMPANY NAME] products are permitted to be sold in interstate commerce throughout the United States.

Insert the following if GMP Statement is required. Products regulated as both a cosmetic and OTC Drug should include each paragraph:

FOR COSMETICS: In the United States of America, such skin care products are legally classified as cosmetics, and the U.S. Food and Drug Administration (FDA) has not promulgated Good Manufacturing Practice regulations (GMPs) for cosmetics. However, the Personal Care Products Council (formerly CTFA) has issued Technical Guidelines in the areas of quality assurance, microbiology, and pharmacology/toxicology, as guidance documents in lieu of formal cosmetic GMPs in keeping with the U.S. cosmetic industry's commitment in the area of self-regulation. To the best of my knowledge and belief, [COMPANY NAME] follows the concepts set forth in the CTFA Technical Guidelines.

FOR OTC DRUG PRODUCTS (e.g., Sunscreens, anti-caries toothpaste, AP/DEOs, anti-dandruff shampoos, etc.): In the United States of America, [RELEVANT PRODUCT(S)] are legally classified as over-the-counter (OTC) drugs, and the U.S. Food and Drug Administration (FDA) has promulgated Good Manufacturing Practice regulations (GMPs) for OTCs. To the best of my knowledge and belief, [COMPANY NAME] follows and complies with the FDA's GMP requirements.

Insert the following if BSE-Free Statement is required:

To the best of my knowledge and belief, the product(s) listed above does not contain materials of bovine, ovine or caprine origin. These products have been manufactured according to all decisions made by the World Health Organization, EU Cosmetics Directive, all applicable U.S. federal, state and local laws and regulations, and all necessary adjustments and controls are applied to minimize the risk.

This further certifies that in the United States of America private companies do not need a license to commence free sale of cosmetic products, and that the United States of America does not have an official laboratory that analyzes cosmetic products prior to such free sale.

[NAME]

[TITLE]

[CITY, STATE]

Subscribed and sworn to before me this ___day of _____, [ENTER CURRENT YEAR]

Notary Public

Example Affidavit