



Review Article

COSMETOVIGILANCE SYSTEM IN USA: A REVIEW

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Article Received on: 12/05/19 Approved for publication: 01/08/19

DOI: 10.7897/2230-8407.1010290

ABSTRACT

The word ‘Cosmetics’ is gaining momentum across last decade as these products are used in significant manner by every individual. The safety monitoring of these products during its usage are critical. Cosmetovigilance system aims to monitor the safety of the cosmetic product after reaching to the consumer. This system has three different public health systems describing the risk related to the ingredients, emergency and routine laboratory quality controls product and notification of Adverse Cosmetic Reports (ACRs). There are three forms to notify ACRs namely Mandatory reporting form, Customer friendly reporting form and Manufacturer reporting form; along with this there is a separate portal for notification of ACRs in USA. Voluntary Cosmetic Registration Program is a reporting system for use by manufacturers, packers, and distributors of cosmetic products that are in commercial distribution in the United States. Cosmetics regulators of developed nations mandated implementation of this cosmetovigilance system. In USA, the FDA has adopted same principles. The purpose of cosmetovigilance is to provide a complete overview of this system in USA starting from collecting the information, the classification, timeline and mode of submission of reports etc. The system is well established and advanced in United States.

Keywords: Cosmetovigilance, ACRs, VCRP, SAE

INTRODUCTION

Cosmetics

FDA defines a cosmetic “as a product (excluding pure soap) intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.” Cosmetics offered for import into the United States must comply with the same FDA laws and regulations as those that are produced domestically in the United States.

New legislations are facing by the Cosmetics manufacturers and distributors more ever before. The new advance technologies are creating new cosmetics with new properties. This increases the demand of cosmetics. The many governments and regulatory bodies are monitoring the manufacture of cosmetics all over the globe. Even more regulatory bodies are there in the globe but the aim of the all regulatory bodies are same it will ensure that the cosmetics should be properly labelled and safe enough to use. In the United States cosmetic regulations are extensive in USA, since it is the one of the largest markets in the world for cosmetic products.¹

Cosmetovigilance

Cosmetovigilance is the ongoing and systematic monitoring of the safety of cosmetics in terms of human health. It is a form of health surveillance, i.e. public surveillance with a public health objective. It thus differs from the surveillance carried out by the industry, whose aim is the safety of the product for commercial

purposes, and differs from peer surveillance. A cosmetovigilance system shall have three different public health systems to discuss about the risk related to the ingredients present in cosmetic products, emergency and routine laboratory quality controls product, notification of ACRs, that means they have created a standard reporting form, pledge of concerning professional categories accredited to report, assessment of the reported ACRs. The aim of cosmetovigilance was to collect the information regarding to collection, registration and evaluation of ACRs.

The law does not require cosmetic products and ingredients, other than color additives, to have FDA approval before they go on the market, but there are laws and regulations that apply to cosmetics on the market in interstate commerce.

The two most important laws pertaining to cosmetics marketed in the United States are

1. Federal Food, Drug, and Cosmetic Act (FD and C Act) and
2. Fair Packaging and Labeling Act (FPLA).^{2,3}

Cosmetics Safety and Labelling Law

The FD and C Act prohibit the marketing of adulterated or misbranded cosmetics in interstate commerce.

“Adulteration” refers to violations involving product composition whether they result from ingredients, contaminants, processing, packaging, or shipping and handling.

Under the FD and C Act, a cosmetic is adulterated if

- It bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under conditions of use as are customary and usual" (with an exception made for coal-tar hair dyes);
- It consists in whole or in part of any filthy, putrid, or decomposed substance";
- It has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health";
- Its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health"; or
- Except for coal-tar hair dyes, "it is, or it bears or contains, a color additive which is unsafe within the meaning of section 721(a)" of the FD and C Act. (FD and C Act, sec. 601)

"Misbranding" refers to violations involving improperly labelled or deceptively packaged products. Under the FD and C Act, a cosmetic is misbranded if

- Its labelling is false or misleading in any particular";
- Its label does not include all required information. (An exemption may apply to cosmetics that are to be processed, labeled, or repacked at an establishment other than where they were originally processed or packed; see Title 21, Code of Federal Regulations, section 701.9.)
- the required information is not adequately prominent and conspicuous;
- Its container is so made, formed, or filled as to be misleading";
- It is a color additive, other than a hair dye, that does not conform to applicable regulations issued under section 721 of the FD and C Act;
- Its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970." (FD and C Act, sec. 602).⁴

FDA Approve Cosmetics before they go on the Market

FDA's legal authority over cosmetics is different from our authority over other products we regulate, such as drugs, biologics, and medical devices. Under the law, cosmetic products and ingredients do not need FDA premarket approval, with the exception of color additives. However, FDA can pursue enforcement action against products on the market that is not in compliance with the law, or against firms or individuals who violate the law.

In general, except for color additives and those ingredients that are prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that

- The ingredient and the finished cosmetic are safe under labeled or customary conditions of use,
- The product is properly labeled, and
- The use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.

Safety of Cosmetics

Companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients. The law also does not require cosmetic companies to share their safety information with FDA.

FDA has consistently advised manufacturers to use whatever testing is necessary to ensure the safety of their products and ingredients. Firms may substantiate safety in a number of ways. FDA has stated that "the safety of a product can be adequately substantiated through (a) reliance on already available toxicological test data on individual ingredients and on product formulations that are similar in composition to the particular cosmetic, and (b) performance of any additional toxicological and other tests that are appropriate in light of such existing data and information.

Recall of a Hazardous Cosmetic from the Market

Recalls of cosmetics are voluntary actions taken by manufacturers or distributors to remove from the marketplace products that represent a hazard or gross deception, or that are somehow defective (21 CFR 7.40 (a)). FDA is not authorized to order recalls of cosmetics, but we do monitor companies that conduct a product recall and may request a product recall if the firm is not willing to remove dangerous products from the market without FDA's written request.⁵

DISCUSSION

The Food, Drugs and Cosmetics Act (FD and C Act) regulates the Cosmetic Regulations in the United States of America. And it contains two categories of products.

- Cosmetics; and
- Drugs including the specific sub-category of over-the-counter (OTC) drugs, which can be sold without prescription.

Among the important differences between requirements for cosmetics in the United States and various other countries are the legal definitions of drugs and cosmetics, restrictions on the use of color additives and other ingredients, and registration requirements. Some products regulated as cosmetics in Europe, for instance, are regulated as drugs in the United States. Sunscreens are a case in point. There also are differences regarding prohibited and restricted ingredients, particularly color additives. Some countries may require cosmetic companies to register their establishments and list products and ingredients with the government; in the United States, cosmetic registration is voluntary but highly recommended.

The Federal Food, Drug and Cosmetic Act (FD and C Act) 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." Included in this definition are products such as skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, toothpastes, and deodorants, as well as any material intended for use as a component of a cosmetic product.

Cosmetic companies may register in the United States through FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP assists FDA in carrying out its responsibility to regulate cosmetics. FDA uses the information to evaluate cosmetic products on the market. Because product filings and establishment registrations are not mandatory, voluntary submissions provide FDA with the best information available about cosmetic products and ingredients, their frequency of use, and businesses engaged in their manufacture and distribution.⁶

Voluntary Cosmetic Registration Program (VCRP)

FDA's Voluntary Cosmetic Registration Program (VCRP) is a reporting system for use by manufacturers, packers and distributors of cosmetic products that are in commercial distribution in the United States. There are two parts to the VCRP filing we can participate in both parts of the program or only one part. The VCRP regulations can be found in 21 CFR, parts 710 and 720.

The VCRP applies only to cosmetic products being sold to consumers in the United States. It does not apply to cosmetic products for professional use only, such as products used in beauty salons, spas, or skin care clinics. It also does not apply to products that are not for sale, such as hotel samples, free gifts, or cosmetic products you make in your home to give to your friends. And these are not required the pre-market approval and companies are not required to submit information on their products or to register cosmetic manufacturing establishments.⁷

Voluntary Registration of Cosmetic Product Establishments

Eligible Person for Registration

The owner or operator of a cosmetic product establishment which is not exempt under §710.9 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 and no registration fee is required.

Time and Place 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.

Form FDA-2511 ("Registration of Cosmetic Product Establishment") is obtainable on request from the Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, or at any Food and Drug Administration district office. The completed form should be mailed to Cosmetic Product Establishment Registration, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740.

Information Requested

Form FD-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; and the type of business (manufacturer and/or packer).

Amendments to Registration

Within 30 days after a change in any of the information contained on a submitted Form FD-2511, a new Form FD-2511 should be submitted to amend the registration. This amendment is also

necessary when a registration is to be cancelled because an establishment has changed its name and no longer conducts business under the original name.

Notification of registrant; cosmetic product establishment registration number

The Commissioner of Food and Drugs will provide the registrant with a validated copy of Form FD-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.

Inspection of Registrations

A copy of the Form FD-2511 filed by the registrant will be available for inspection at the Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740.

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 labelling or advertising that creates an impression of official approval because of registration or possession of a registration number will be considered misleading.

Exemptions

The following classes of persons are not requested to register in accordance with this part 710 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) Person 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.

Serious and Unexpected Adverse Event Reporting for Cosmetics In General

The Secretary shall by regulation require that a domestic or foreign manufacturer, packer, or distributor whose name appears on the label pursuant to section 602(b) (1) of a cosmetic marketed in the United States submit to the Secretary under subsection (b) a report containing information received concerning a serious and unexpected adverse event in the United States allegedly associated with the use of the product.

Submission of Reports

A serious and unexpected adverse event report shall be submitted to the Secretary no later than 15 business days after information concerning the adverse event is received at the place of business labelled on the product under section 602(b) (1).

Contents

No such report shall be submitted unless the person submitting the report has been able to verify:

- a) an identifiable patient
- b) an identifiable reporter
- c) a suspect cosmetic product and
- d) a serious and unexpected adverse event.

The person submitting the report may include in the submission any additional pertinent information and may supplement the report with additional information at a later time.

Definitions

A 'serious' adverse event is one that results in

- i. death;
- ii. a life-threatening experience;
- iii. inpatient hospitalization
- iv. a persistent and significant disability or incapacity; or
- v. congenital anomaly or birth defect;

Rules of Construction

1. A serious and unexpected adverse event report (including all information submitted in the initial report or added later) submitted to the Secretary under subsection.
 - A. Safety report under section 756 that is subject to the provisions of that section
 - B. A record about an individual under section 552 a of title 5, United States Code and a medical or similar file the disclosure of which would constitute a violation of section 552 (b) (6) of such title 5, and shall not be publicly disclosed.
2. The submission of a serious and unexpected adverse event report in compliance with the above-mentioned sections shall not constitute an admission that the cosmetic involved caused or contributed to the adverse event.
3. The label of a cosmetic shall bear the domestic telephone number through which the person whose name and place of business appear on the label may receive a report of a serious and unexpected adverse event."⁸

There are Three Types of Forms are There for the Reporting

- Form FDA 3500 (voluntary)
- Form FDA 3500 A (mandatory)
- Form FDA 3500 B (consumer-friendly)

Form FDA 3500 (voluntary)

Form FDA 3500 may be used by health professionals or consumers for Voluntary reporting of adverse events, product use errors, product quality problems, and therapeutic failures of cosmetics (such as moisturizers, makeup, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos)

Adverse events involving investigational (study) cosmetics, such as those relating to Investigational New Drug (IND) applications, including those for cellular products administered under IND, should be reported as required in the study protocol and sent to the address and contact person listed in the study protocol.

They should generally not be submitted to FDA MedWatch as voluntary reports.⁹

FDA 3500 A (Mandatory)

The 2 most recent bills presented in House of Representatives "Cosmetic Safety Amendment Act of 2012" & "Safe Cosmetics and Personal Care Products Act of 2013" include:

- a) Mandatory report for the "Serious and Unexpected" adverse events (Cf. bill of 2012) and "Serious" adverse events (bill of 2013)
- b) Within 15 business days
- c) To the "Secretary of Health and Human Services"¹⁰

Form FDA 3500 B (Consumer-Friendly)

Are encouraged to report adverse reactions and quality defects

- a) Through the Med Watch Web site "Bad reactions to cosmetics? Tell FDA" (FDA Form 3500A – Costumer Voluntary reporting)
- b) Through the Med Watch Hotline
- c) By contacting the FDA Consumer Complaint Coordinator of their state ¹¹

Labelling and Warnings

FPLA and FD and C Act regulate the labeling of Cosmetics in United State of America. As per the regulations, cosmetic products which are ready to retail sale required to carry an ingredient declaration on their outer package, while those not distributed for retail sale. The US Department of Commerce requires the Country of origin labelling for imported cosmetic products and also the Cosmetic ingredients must be listed by their established name (INCI names) as laid out in the Cosmetics; the label statement should appear on inside and outside of the wrapper or container.

Cosmetic Product Warning Statements

Establishment of warning statements

- a) The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.
- b) The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to establish or amend, under subpart B of this part, a regulation prescribing a warning for a cosmetic. Any such petition shall include an adequate factual basis to support the petition, shall be in the form set forth in part 10 of this chapter, and will be published for comment if it contains reasonable grounds for the proposed regulation.

Conspicuousness of Warning Statements

- a) A warning statement shall appear on the label prominently and conspicuously as compared to other words, statements, designs, or devices and in bold type on contrasting background to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, but in no case may the letters and/or numbers be less than 1/16 inch in height.
- b) If the label of any cosmetic package is too small to accommodate the information as required by this section, the

Commissioner may establish by regulation an acceptable alternative method, e.g., type size smaller than 1/16 inch in height.

Labeling of cosmetic products for which adequate substantiation of safety has not been obtained.

Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

Warning -The safety of this product has not been determined.

Cosmetics in self-pressurized containers

The label of a cosmetic packaged in a self-pressurized container and intended to be expelled from the package under pressure shall bear the following warning:

Warning

Avoid spraying in eyes; contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120 °F. Keep out of reach of children.

Feminine Deodorant Sprays

(a) For the purpose of this section, the term “feminine deodorant spray” means any spray deodorant product whose labelling represents or suggests that the product is for use in the female genital area or for use all over the body.

(b) The label of a feminine deodorant spray shall bear the following statement:

Caution

For external use only; spray at least 8 inches 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.

Foaming Detergent Bath Products

(a) For the purpose of this section, a foaming detergent bath product is any product intended to be added to a bath for the purpose of producing foam that contains a surface-active agent serving as a detergent or foaming ingredient.

(b) The label of foaming detergent bath products within the meaning of paragraph (a) of this section, except for those products that are labelled as intended for use exclusively by adults, shall 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 use if rash, redness, or itching occurs. Consult your physician if irritation persists. Keep out of reach of children.

Coal tar hair dyes posing a risk of cancer

(a) The principal display panel of the label and any labelling accompanying a coal tar hair dye containing any ingredient listed in paragraph

(b) Of this section shall bear, in accordance with the requirements of §740.2, the following:

Warning

Contains an ingredient that can penetrate your skin and has been determined to cause cancer in laboratory animals

Sun tanning Preparations

The labeling of sun tanning 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.

Testing and Safety

Cosmetics imported into the United States, both ingredients and finished products, must meet the same criteria for safety and labeling as those manufactured domestically.

FDA does not pre-approve cosmetic products or ingredients, with the important exception of color additives. However, cosmetic firms are responsible for marketing safe, properly labeled products; using no prohibited ingredients; and adhering to limits on restricted ingredients. It is also considered good practice to follow industry safety guidelines and recommendations.

Before marketing a product containing a color additive in the United States, it is essential to determine whether the additive is approved for its intended use. A number of color additives must be certified for purity in FDA labs if they are to be used legally in a product marketed in the United States.

Although U.S. regulations do not specify any particular testing regimens for cosmetic products or ingredients, it is the cosmetic company's responsibility to substantiate product and ingredient safety prior to marketing¹²

CONCLUSION

Cosmetovigilance is a complex process and robust systems, essential to undertake the safety activity. The foundation for building a robust Cosmetovigilance system has already been done to some extent by the US FDC Act. However, the system needs to be refined with the help of Cosmetovigilance experts in collaboration with information technology. With more and more clinical research now being conducted, gathering of information regarding reporting and evaluation of Cosmetics related ACRs are deemed essential. It will be worth full to invest in a robust Cosmetovigilance system, which will enable assessors and decision makers to analyze safety and effectiveness of cosmetics.

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Cite this article as:

K M Vinaykumar and M P Venkatesh. Cosmetovigilance system in USA: A Review. *Int. Res. J. Pharm.* 2019;10(10):8-13
<http://dx.doi.org/10.7897/2230-8407.1010290>

Source of support: Nil, Conflict of interest: None Declared

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