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Case Study

A CASE STUDY: COSMETIC RULES ON SAFETY AND OBJECTIONABLE CLAIMS CONSIDERED TO COSMETICS IN INDIA & USA

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ABSTRACT

Cosmetics have been part of people's lifestyle since long and nonetheless a very important part of Women in particular. Expression of identity can be through several things like clothes, jewellery, fashion, style, use of cosmetics to enhance or alter looks and beauty is the most common and most important way to create an identity for themselves.Cosmetics are being used today at an unprecedented rate by all sections of society and because cosmetics are manufactured using ingredients which are mainly chemicals, it becomes a necessity to govern the quality and safety of such products. In India, that role is played by Central Drugs Standard Organization which regulates Cosmetics under Drugs and Cosmetics Act, 1940 and rules made thereunder. Similarly, every nation has its own regulation and rules to govern quality and safety of Cosmetic products.

It is pertinent to mention here that apart from quality and safety of Cosmetics the claims made on the labels of these products are becoming equally important. The Cosmetics are one of the most widely used Consumer products and any misleading or tall claim made to sell Cosmetic product is nothing less than a fraud. But most importantly, flouting the rules and regulations to present Cosmetics having Drugs like effects is becoming an ever increasing and serious problem which needs to be addressed through strict implementation of Drugs and Cosmetics Act, 1940 and Rules made there under.

The current review is an attempt to give a glimpse of the Cosmetic Safety standards in India, Penalties associated with violating Safety standards of Cosmetics Rules, 2020 and Objectionable claims issues surrounding the current Cosmetics Market in India which will help the readers including Cosmetic Industry to carve their niche in compliance to the law of the land as well as ensuring Consumer safety.

HISTORY

As far as the history of Cosmetic Industry in India is concerned then it can be traced back to Indus Valley Civilization. According to an article published by Mr. Kunda B. Patkar in the Indian Journal of Plastic Surgery, use of Cosmetics in India dates back to Indus Valley Civilization, 2500 and 1550 B.C. which were all herbal in nature. The chemical Cosmetics were first introduced in India during the British rule and as they have instant results these chemical-based cosmetics became popular than herbal cosmetics in no time. But during that time there were no Cosmetics brands and no standards. The Cosmetics at that time contained carcinogenic ingredients in addition to use of toxic metals like lead and mercury with no limits. Later on, post-independence era saw introduction of Cosmetic brands such as Lakme which was then followed by other Cosmetic Companies. But the actual revolution was seen after the Indian economic reforms of 1991. Theinternational brands likeRevlon, L'Oreal, M.A.C., Maybelline and Cliniqueentered into India post 1991. This was also reflected in Cosmetic Advertisement. This reach was further enhanced by E-commerce platforms and use of Internet.(https://shilpaahuja.com/indian-beauty-industry-evolution/)

In 2017, a study by Assocham and research agency MRSS India pegged the value ofIndian Cosmetic Industry to 6.5 Billion USD, which further estimated that in the year 2035, the same industry may touch a revenue of 35 Billion USD. This is huge in terms of

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revenue and attracts a lot of international players in Indian Cosmetic Market. (https://shilpaahuja.com/indian-beauty-industry-evolution/)

3. Definition of Cosmetics and Cosmetic regulation in India

The Drugs and Cosmetics Act, 1940defines Cosmetics as any article rubbed, poured, sprinkled or sprayed on, or introduced into, or applied to, the human body or part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance. It includes any article intended for use as a component of cosmetic.

In 1930 the Government of India constituted the Drugs Enquiry Committee; it was fortunate that a person of Colonel Chopra's (R.N. Chopra) vision was chosen to chair it. The recommendations of the committee greatly helped in several of the much-needed pharmaceutical developments in the country. The Drugs Act 1940 was enacted on 10th April 1940. However, at the time of enactment, cosmetics were not mentioned therein. In order to regulate the cosmetics products in India, in 1962, Act 21 was propagated to cover 'Cosmetics' and definition of cosmetics in the Drugs and Cosmetics Act, 1940 to cover whole of India. The provisions regarding manufacture, sale, distribution or import of cosmetics were introduced in the Actin 1982.

In order to implement the provisions specified under the Drugs and Cosmetics Act, 1940, certain set of rules named Drugs and Cosmetics Rules, 1945 was published vide notification no. F.28-10/45-H(1) on 21.12.1945. Subsequently the Drugs and Cosmetics Rules, 1945 was amended vide G.S.R. 1183 dated 17.08.1964 with regard to implementation of provisions of manufacture of cosmetics as specified under chapter IV of the Drugs and Cosmetics Act, 1940.

Cosmetic Import regulations were introduced under the Drugs and Cosmetics Rules, 1945 on 19.05.2010 vide G.S.R 426(E) dated 19.05.2010. However, the actual implementation of the said provisions came into force from 01.04.2013. Central Drug Standard Control Organisation (CDSCO) headed by Drugs Controller General (India) regulates the import of cosmetics vis-à-vis the Drugs and Cosmetics, Act and rules therein.

Previously, cosmetics in India were regulated under the Drugs and Cosmetics Rules, 1945. For separate codification and updation of the cosmetics rules, the Govt. of India has published vide G.S.R. 763(E) dated 15.12.2020 which are a set of separate rules called Cosmetics Rules, 2020, that governs regulation of cosmetics in India.

4. Case Studies-Unsafe Cosmetics, Misleading Cosmetic Label Claims and Advertisements

a. Johnson and Johnson Baby Powder: In 2018, an article published by Reuters claimed that they had examined companies internal document which showed that the company's iconic product was at times found to be contaminated with a carcinogen named asbestos and that Johnson and Johnson concealed that information both from the public and the regulator. Today, Johnson and Johnson face thousands of lawsuits across the globe alleging that its talc product caused cancer. It is clear from such report that the issue is not limited to small companies, and safety took a back seat when it came to their revenue and profit. And therefore, Cosmetic regulations and Cosmetics safety concerns are well founded. (https://www.reuters.com/investigates/special-report/johnsonandjohnson-cancer/)

b. Sensodyne and Colgate: In 2019, State FDA of Maharashtra seized toothpastes worth crores of rupees for allegedly making misleading claims on their product label. The claims were made on two Toothpaste products-"Sensodyne Fluoride toothpaste, Fresh Gel and its variants made claims of repair and protection, clinically proven relief, and daily protection for sensitive teeth inscribed on the carton and the tube. Colgate Anticavity Toothpaste, Sensitive had 24/7 sensitivity protection and clinically proven relief inscribed". Though the matter is sub judicenow, but it really brings in light the importance of Cosmetics Regulations from Consumer perspective. (https://www.thehindu.com/news/cities/mumbai/fda-cracks-down-on-sensodyne-colgate-over-clinical-claims/article26738834.ece)

c.)Procter & Gamble Hygiene & Health Care Limited (Head & Shoulders Anti-Dandruff 2 in 1 Cool Menthol Shampoo + Conditioner): The advertisement claimed that the product straightens hair but in fact it only smoothens them. (https://bestmediainfo.com/2020/05/110-objectionable-ads-withdrawn-after-asci-intervention-in-january-2020/)

d.)Hindustan Unilever Ltd (Sunsilk Conditioner): The advertisement claimed that the product keeps hair set all day. The claims were not substantiated and were objected to by the authority.

e.) HINDUSTAN UNILEVER HAND SANITIZER: A show-cause notice was issued by DCGI over false claims by Hindustan Unilever for Hand sanitiser. The product claims to boost immunity and prevent Covid-19. It asserts to improve the immunity by the use of hand sanitizer which in turn prevents the virus.This was a clear contravention of Drugs and Cosmetics Act and Rules made thereunder as the product was licensed under Cosmetic was being advertised as drug by the firm. It was concluded that the Lifebuoy's claims of hand sanitizer were false and misleading in nature as the product cannot boost immunity against virus. (https://lexforti.com/legal-news/advertising-standards-council-of-india-asci/)

All the firms big or small try to mislead the consumer and the regulator either through their tall claims with no satisfactory evidence or through misleading claims by presenting cosmetics as drug products in public domain.

The abovecases are only a few of the endless examples to provide an insight into how Cosmetics safety and Misleading Cosmetic Claims needs to be addressed with revolution in mass communication and social media expansion.

5. Cosmetics Rules, 2020: An Emphasis on ensuring safety of Cosmetic products.

As it was mentioned earlier that the cosmetics Industry is both Herbal and Chemical based, but it is noteworthy that the chemical Cosmetics are the ones which dominates the market. And consequently, such cosmetics poses risks to consumers if not regulated. Therefore, Cosmetics Rules 2020 has provisions to ensure that the cosmetics manufactured in India as well as imported in India meets the safety requirements and functions exactlyas claimed by the manufacturers.The several measures with respect to safety aspects of Cosmetics as provided in Drugs and Cosmetics Act, 1940 and Cosmetics Rules, 2020 made thereunder are as follows:

A) Provisions with regard to safety of Cosmetics Products:

The approval for import or manufacture of new cosmetic as per terms of Rule 32 of the Act entails the following:

(i) An application to the Central Licensing Authority (CLA) in Form COS- 12 accompanied with the required fee to be made by any person intending to manufacture or import cosmetics. It has to be accompanied with requisite data on safety norms and the relative effectiveness.

(ii) The CLA, if satisfied that the cosmetic if manufactured or imported is safe and effective, may issue a prior permission in Form COS-3, subject to the condition specified therein.

(iii) This Form COS-3 along with import application under Chapter III or manufacture under Chapter IV shall be furnished.

(iv) IS 4011 : 2018 methods of test for safety evaluation of cosmetics, published by the Bureau of Indian Standards from time to timespecifies the test methods and analysis thereof if cosmetics to be adhered to by the manufacturer.

B) Provisions with respect to misleading claims on Cosmetic product labels:

Rule 36 of the Act prohibits false or misleading claims. Cosmetic cannot claim or imply to claims any idea which may be false or misleading to the end user.

C) Provisions w.r.t. Sub-standard Cosmetics.-Section 8 and 16 of the Drugs and Cosmetics Act, 1940 prescribes standards of quality for cosmetic products.

i. Misbranded cosmetics.-A cosmetic is considered misbranded under the following conditions

(a) it contains an unprescribed colour.

The labelling of the cosmetic is not as per the provisions.

The labelling or the container or any other accompaniment bears a false or misleading claim or statement.

ii. Spurious cosmetics.-A cosmetic is considered spurious under the following conditions—

(a) It is imported with the same name as its counterpart.

(b) It is an imitation or substitute or in any way resembles another cosmetic or the label or container is likely to deceive the user. It should clearly and noticeably be marked as to reveal its true nature and how it is different from the other cosmetic.

(c)The label or container mentions the manufacturer as an individual or company which is fake or fictitious or does not exist.

(d) It wrongfully claims to be manufactured by a company which is not producing it.

iii. Adulterated cosmetics. - A cosmetic is considered adulterated under following conditions-

(a) The cosmetic contains any dirty, fetid or putrid decomposed or decayed substance.

(b) The cosmetic is manufactured, packaged or stored in unhygienic or unsanitary conditions leading to contamination or health hazard.

(c) The container of the cosmetic is made of any harmful or poisonous substance wholly or partly which may make the product harmful.

(d) The cosmetic is of a colour not prescribed under the rules.

(e) The cosmetic contains an ingredient which is toxic or harmful or hazardous to health.

(f) The cosmetic has been deleted or mixed with a substance to mitigate the quality or the potency.

6. Standards of Cosmetics in India as per Drugs and Cosmetics Act, 1940 and rules made there under:

A) Standards of Cosmetics

• Cosmetic whether imported or manufactured should comply with the provisions specified in the Ninth Schedule or any other applicable standards of quality and safety as per Rule 39.

• Cosmetic not covered under the Ninth Schedule shall conform to the rules, standards and regulations of the country of origin.

B) Standards for cosmetics raw materials/ingredients

• Bureau of Indian standards has published Indian Standard IS 4707 for cosmetics raw materials in two parts:

• IS 4707 (Part 1) : 2020 (Classification of Cosmetic Raw Materials and Adjuncts, Part 1 Colourants)

• IS 4707 (Part 2) : 2017 (Classification of Cosmetic Raw Materials and Adjuncts, Part 2 List of Raw Materials Generally not Recognized as safe for use in Cosmetics).- The raw materials and adjuncts prescribed in this standard have been classified as follows:

IS 4707 Part 2	
Annex A	Raw materials which cannot be ingredients of a cosmetic product.
Annex B	Raw material which can be ingredients subject to conditions and restrictions specified.
Annex C	Restricted Preservatives which are part of cosmetic products.
Annex D	Restricted cosmetic products whichcontain UV filters.

• Synthetic Organic colours and Natural Organic Colours specified shall not contain more than: -

(i) more than 2 parts per million of Arsenic calculated as Arsenic Trioxide.

(ii) more than 20 parts per million of lead calculated as lead.

(iii) more than 100 parts per million of Heavy Metals other than lead calculated as the total of the respective metals.

• Any cosmetic having hexachlorophene as its ingredient shall not be manufactured or imported barring soaps, in which case it may be used in concentration less than or equal to one percent weight by weight.

• Cosmetics manufactured or imported shall contain mercury in the following proportions:

a) Eye cosmetics: level of mercury shall not exceed 70 parts per million (0.007%) of mercury calculated as metal or preservative.

b) Any other finished cosmetic product – unintentional mercury shall not exceed 1 part per million.

• Lead and Arsenic compounds cannot be used for colouring.

• No animals to be used for testing of Cosmetics.

7. Standard for cosmetics safety evaluation

BIS has published the standard IS 4011:2018 "Method of Test for Safety Evaluation of Cosmetics. This standard specifies the methods of test for safety evaluation of cosmetics. The type of tests to be performed for particular type of cosmetics is given as:

Sr. No.	Test	Types of products
1	Skin irritation test (Patch test in human)	Skin and hair products and lip products.
2	Photo irritation tests (Photo patch test in human)	Skin and hair products and lip products showing a potential of causing photo irritation.
3	Relevant in-vitro/ex-vivo tests from those listed in Annex B (Alternate methods for safety testing)	Skin and hair products, lip products and oral care products prior to human participant studies.

Alternate methods for safety testing of cosmetics (as per Annex B of IS 4011: 2018)

Toxicity assessment of ingredients of cosmetic products can be made through the following tests:

1. Skin Corrosion

2. Skin Irritation

3. Skin Sensitization

4. Eye Irritation

5. Photo Toxicity

6. Skin Absorption

7. Genotoxicity

8. Offences and Penalties.-

A. Import of Cosmetics.-

S.No.	Offence	Penalty	
	First Conviction	Subsequent Conviction	First Conviction
1.	Spurious Cosmetic	Imprisonment upto 3 years and upto Rs 5000 fine.	imprisonment upto 5 years and/or upto 10,000 fine
2.	Import of Prohibited Cosmetic	punishable with imprisonment up to 6 months or Rs 5000/- fine or both.	punishable with imprisonment up to 1 year or fine upto Rs 1000/- or both
3.	Contravention of the	punishable with	punishable with

	provisions of any notification issued under section 10A	imprisonment up to 3 years or fine upto Rs 5000/- or both	imprisonment up to 5 years or fine upto Rs 10,000/- or both.

B. Manufacture, Sale etc., of Cosmetic.-

S.No.	Offence	Penalty	
		First Conviction	Subsequent Conviction
1.	Spurious or Adulterated Cosmetic	punishable with imprisonment extending to 3 years and a fine not less than Rs 50,000/- or 3 times the value of the confiscated cosmetic whichever is more	punishable with imprisonment extending to 2 years or with fine upto Rs 2000/- or both
2.	Contravention of any provisions of Chapter 4	punishable with imprisonment extending to 1 year or fine extending to Rs 20,000/- or both.	
3.	Contravention of the provisions of any notification issued under section 26A	punishable with imprisonment upto 3 years and a fine extending to Rs 5000/-	

9. Prohibition on Import or manufactured of certain cosmetic products in India.-

Provisions for prohibition on certain cosmetic products are specified in Rule 18 of the Cosmetic Rules 2020.

1) Any cosmetic whose manufacturer, sale or distribution is prohibited in the country of origin shall not be imported with the same name or any other name except for examination, tests or analysis.

2) Any cosmetic whose use before/use by date mentioned on the label or container is later than 6 months from the date of import shall not be imported.

3) Any cosmetic with hexachlorophene as ingredient shall not be imported.

4) Any cosmetic tested on animals after 12th Nov 2014 shall not be imported.

10. Cosmetics Regulation in USA

Cosmetics in USA are governed by the Federal Food, Drug and Cosmetic Act (FD&C Act) and Fair Packaging and Labelling Act (FPLA).

11. Definition of Cosmetic as per USFDA.-

The Federal Food & Cosmetic Act defines Cosmetics as:

1) any articles intended to be used for rubbing, pouring, sprinkling or spraying or introducing into or applying to the human body or any part thereof for cleansing, beautifying, enhancing attractiveness or altering appearance.

2) Any articles or products for using as components of such articles or products excluding soap.

12. Regulatory Provisions for Cosmetics in USA -

FDA regulates cosmetics under the provisions of US Law even though the cosmetics and their ingredients do not require premarket approval from the FDA. Color additives are the only exception. Any non compliance observed or reported on the cosmetics encourages enforcement action by the FDA.

A manufacturer is allowed to use any ingredient for formulating a cosmetic product except color additives and any other ingredients which is prohibited or restricted by US Cosmetic regulation subject to the following conditions:

• the ingredients as well as the finished or the final cosmetic product is safe as per the conditions of use labelled on the product,

• the product is suitably labelled, and

• no ingredient used in the product makes it adulterated or misbranded under US laws.

Registration of cosmetics manufacturers/establishments with FDA is not mandatory under the US Laws.

However, there is a databasenamed Voluntary Cosmetic Registration Program (VCRP) by FDA, where cosmetic firms participate in the online registration process and can file products related details and information that are currently being marketed in the United States including their manufacturing and packaging locations in the VCRP database.

13. Labelling Provisions for CosmeticProducts in US.-

Cosmetic products in USA are labelled in accordance with the USFDA regulation named Federal Food, Drug, and Cosmetic Act

(FD&C Act) and the Fair Packaging and Labelling Act (FPLA). The primary objective or purpose of the provisions of these laws is to safeguard or protect consumers in US from any potential health hazards or frauds related to Cosmetic products and to ensure that the consumers are well informed before they buy these products for personal use.

The provisions of the aforementioned Acts lay down the conditions which make the cosmetic product misbranded. It is illegal to market a misbranded product in US. A strict regulatory action is taken as per the laws, if:

• its labelling is false/misleading in any ways,

• its label fails to deliver requisite information as per the Law,

• its requisite label information is not displayed appropriately, and

• its labelling information violates the provisions of the Poison Prevention Packaging Act of 1970 [FD&C Act, sec. 602; 21 U.S.C. 362].

It is pertinent to mention here that, under the law, there is no compulsion for pre-market approval of cosmetic product labelling matter. Instead, it is manufacturer's/ Distributor's responsibility to make sure that all the products are labelled as per the provisions specified under the Law. Any violation of the rules/provisionswith respect to labelling requirements will result in a misbranded product.

The main product label should have the following printed on it :

• An identity statement, listing the nature and use of cosmetic product by means of common/usual name, a detailed name, a promotional name understood by the public, or an illustration [21 CFR 701.11].

• Andefinite or accurate statement of the weightage or the measure or the count or a combination of numerical count, weight or measure. [21 CFR 701.13].

The following information must be displayed or printed on the information panel:

• Name and place of business. This could be the manufacturer, a packer, or a distributor. This may include the street address, city, state, and pin Code. Street address can be be omitted if it is already listed in the current phone directory or the city directory [21 CFR 701.12(a)].

• Distributor statement. If the name and address does not belong to the manufacturer, then the label must mention "Manufactured for..." or "Distributed by...," or similar other wording providing the facts [21 CFR 701.12(c)].

• Material facts. The failure to reveal any material facts is one form of misleading label and therefore such product can be called misbranded [21 CFR 1.21]. An example is directions for safe use, which would mean that a product could be unsafe if used incorrectly.

• Warning and caution statements. These must be prominently and noticeably printed on the label of the cosmetic product [21 CFR part 700],[21 CFR 740.1].

• Ingredients. If the product is being sold on a retail basis to consumers, even then it has to be labelled "For professional use only" or words to that effect, the ingredients must be printed on the information panel, in a descending order of predominance. [21 CFR 701.3]. In case, the product is also a drug, then the label must comply with the provisions given for both OTC drug as well cosmetic ingredient labelling.

14. Color Additives.-

In USA, only FDAapproved color additives are permitted in cosmetic productsand that too for the intended use. If some cosmetic contains any color additive, then it must complywith the FDA's laws and requirements for its approval/certification, including identity, specifications, end use and restrictions. The FDA maintains two categories of approved color additives which are as follows: first are those color additives which are subject to certification and second are those color additives which are not subject to certification. This means that for color additives which are subject to certification, the FDA will be verifying the Color Identification Number (CIN) at the time of import of Cosmetic products into USA.

Some Basic Requirements for Color Additives.-

If a cosmetic product (except coal tar, hair dyes) is comprised of a color additive, it requires compliance with the following basic conditions as per the provisions of the FD&C Act:

• Approval. All color additives used in cosmetics (or any other FDA-regulated product) must have FDA approval as per the provisions of a regulation specifically addressing a substance's use as a color additive, specifications, and restrictions.

• Certification. Apart from approval, a few color additives used for cosmetics or any other FDA regulated products have to be batch certified by FDAwhich are to be marketed in the U.S.

• Identity and specifications. All the color additives must meet the requirements of Code of Federal Regulations (CFR) for identity and specifications.

• Use and restrictions. Color additives must be used only for the approved intended uses as stated in the provisions pertaining to them. Theseprovisions also specify additional restrictions for certain colors additives, such as the maximum permissible concentration in the finished product.

15. Prohibitions for Cosmetics in US.-

The provisions of US FD&C Act, prohibits the marketing of adulterated or misbranded cosmetics.

"Adulteration" refers to non-compliance involving product composition- which may result either from ingredients or contaminants or processing, or packaging, or shipping and handling. As per US FD&C Act, a cosmetic is considered adulterated if--

• it possess any poisonous, toxic or lethal or deleterious ingredient or substance which may cause injury to the user under the conditions of use printed on the product label or mentioned in conventional conditions of use (except coal-tar hair dyes).

• the cosmetic contains any dirty, filthy, fetid or putrid, decomposed or decayed substance wholly or partly.

• the product has been manufactured or packaged in unhygienic or insanitary conditions making it contaminated or a health hazard.

• the container of the product is made with any poisonous, lethal or toxic or deleterious substance or ingredients wholly or partly which make the contents a health hazard or injurious or

• the product possess or contains a color additive with exception of coal-tar hair dyes, which may be unsafe for use as per section 721(a) of the FD&C Act. (FD&C Act, sec. 601)

"Misbranding" - A cosmetic product may be misbranded for not complying with labelling or packaging cosmetic product regulations. A product may be misbranded under following conditions --

• the label of the cosmetic product displays any false content or any misleading content.

• the label lacks complete information which is required to be displayed. Cosmetics which have to be processed, repackaged or labelled in an establishment different from original place of processing or packaging are exempt.

• the container of the product has been manufactured or made or formed or filled in a way that it may mislead the consumer.

• it is a color additive (except hair dye) which does not require compliance of the provisions of FD&C Act.

• the packaging or the labelling of the cosmetic product does not comply with the provisions of Sec 3 or 4 of the Poison Prevention Packaging Act of 1970.

Further under the provisions of FD&C Act, a product may be called misbranded on failure to give material facts. For example, any directions for safe use and warning statements must be given to ensure a product's safe use.

16. Conclusion

It is really a matter of concern and further discussion that though there are comprehensive regulations with respect to Cosmetic safety, Cosmetic Standards and provisions for penalty but irrespective of the country and brand size of the Cosmetic firm there are new cases of Contravention everydaywhich poses serious challenge to the rights of Consumer to have safe Cosmetic products. Nonetheless, the misleading advertisements and Misleading claims on Cosmetic labelshave become a nuisance as there cannot be a well-defined outline to describe about what could be misleading to Consumers as Cosmetics are entirely Consumer products which needs a bit of promotion to move ahead in such a competitive market.But, if the Cosmetics are looked into, just from the Consumer perspective, then current regulations are enough but if Regulator is taken into account, then the enforcement part needs to be further strengthened. The Safety itself is a combined responsibility of both the Regulator and the Cosmetic Manufacturer while moral and ethical obligation lies only with Cosmetics Industry.

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