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To Study the Registation Process of Herbal Cosmetics Under CDSCO Under India

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Abstract: *The popularity of herbal cosmetics is rising as consumers increasingly prefer products that are natural, safe, and free from synthetic chemicals. However, many products marketed as "herbal" lack proper quality validation or regulatory approval, posing risks to consumers. This study focuses on understanding the regulatory pathway for herbal cosmetic registration under the Central Drugs Standard Control Organization (CDSCO) in India. It explains the legal requirements, mandatory documentation, licensing procedures, and quality standards such as Schedule M-II and BIS guidelines. By outlining the approval process for both manufacturing and import, the study highlights the importance of regulation in ensuring product safety, authenticity, and market transparency.*

Keywords: Herbal Cosmetics, CDSCO (Central Drugs Standard Control Organization), Drugs and Cosmetics Act, 1940, Schedule M-II (Good Manufacturing Practices), BIS (Bureau of Indian Standards),Cosmetic Registration Process

I. INTRODUCTION

Herbal cosmetics are personal care products formulated using plant-based ingredients that offer cleansing, beautifying, or nourishing effects. Unlike synthetic cosmetics, these formulations align with holistic wellness traditions such as Ayurveda and emphasize long-term benefits with minimal side effects. Due to increasing awareness of natural products, the herbal cosmetic sector in India has grown rapidly. To maintain product quality and protect consumers, regulation is essential. The Central Drugs Standard Control Organization (CDSCO) governs the licensing and approval of herbal cosmetics under the Drugs and Cosmetics Act, 1940. Understanding this regulatory process ensures correct labeling, standardized manufacturing, and safe distribution of herbal cosmetic products in India.

Aim & objectives

Aim

The aim of this study is to analyse and understand the complete registration process of herbal cosmetics under CDSCO in India, focusing on legal requirements, documentation, licensing procedure, and quality standards. The study further aims to promote safe, compliant, and standardized herbal cosmetic manufacturing and import practices.

Objectives

1. To understand the regulatory framework and registration process of herbal cosmetics under CDSCO in India.
2. To ensure consumer safety, quality control, and compliance with labeling and ingredient standards.
3. To analyze global regulatory practices and compare them with India's system for benchmarking.
4. To identify challenges and gaps in the registration process for herbal cosmetics.
5. To promote awareness among manufacturers and importers regarding proper documentation and licensing procedures.

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II. METHODOLOGY

The methodology chapter provides a complete explanation of how this research was conducted, including the procedures followed, data sources used, documents reviewed, regulatory verification, and experimental steps for the preparation of a herbal cosmetic prototype. The chapter integrates two complementary research approaches:

Research Type	Description	Purpose
Type A –Regulatory / Documentation Study	Analysis of CDSCO cosmetic regulations, Forms (31/32/42/43), BIS standards, labeling rules, and GMP requirements.	To understand the registration process of herbal cosmetics under CDSCO in India.
Type B –Experimental / Manufacturing Methodology	Demonstration of herbal cosmetic manufacturing workflow (general), QC testing, labeling, documentation, packaging.	To understand formulation development and compliance requirements before applying for CDSCO approval.

A. Research Design

This study follows a sequential, mixed-method methodology consisting of:

1. Exploratory Stage (Regulatory Study) Reviewing CDSCO Acts, Rules, BIS standards, and international cosmetic regulatory documents.
2. Experimental Stage (General Manufacturing Workflow)

Demonstration of how herbal cosmetic products are manufactured, packaged, tested, and documented before regulatory submission.

3. Analytical Stage (Data Evaluation)

Analysis of compliance, identification of regulatory gaps, comparison with global regulations.

B. Methodology Framework

Stage	Activity	Output
Stage 1	Literature & Regulatory review	Understanding CDSCO pathways
Stage 2	Data extraction (Forms, BIS, Schedule M-II)	Documentation checklist
Stage 3	General herbal cosmetic formulation procedure	Prototype batch record
Stage 4	Quality control & safety evaluations	Stability & microbiological test report
Stage 5	Regulatory documentation preparation	Label, Form 31/32/42/43 templates
Stage 6	Final analysis	Interpretation and validation

Table 1: Research Inputs and Output Matrix

Component	Inputs Used in Research	Expected Output
Regulatory Documentation Study (CDSCO)	Drugs & Cosmetics Act 1940, Cosmetic Rules 2020, CDSCO SUGAM portal, BIS Standards	Licensing pathway (Form 31/32/42/43), regulatory roadmap
Manufacturing Methodology	Raw materials, base formulation ingredients, standard equipment	Herbal cosmetic prototype development methodology
Quality Control & Safety Testing	BIS IS:4011, Schedule M-II, microbial & stability testing methods	QC checklist + Certificate of Analysis format
Labeling & Packaging	Rule 148 labeling rules, packaging compatibility	Finished pack regulatory label compliance

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C. Data Collection Strategy

1) Primary Data Collection (Regulatory and Experimental)

Interaction with formulation scientists and regulatory executives
Observation of cosmetic production flow in a GMP certified facility
Study of CDSCO portal (SUGAM)

2) Secondary Data Collection

CDSCO guidelines (Cosmetic Rules 2020)
BIS Standards (IS 4011 & IS 4707 Part I & II)
WHO Guidelines – Quality Control of Herbal Raw Material (2022)
Peer-reviewed scientific literature (2018–2024)

Tools used:

Google Scholar
PubMed
CDSCO SUGAM portal
BIS database

D. Experimental Methodology (General Herbal Cosmetic Manufacturing)

1) Objective of Experimental Section

To demonstrate the standard manufacturing steps applicable to any herbal cosmetic:
Cream / lotion / conditioner / shampoo / gel / facewash
No product-specific composition is used; instead, universal formulation methodology is shown.

2) Sample Generic Base Formulation (Option B Requirement)

This table represents a general cosmetic matrix applicable to any herbal cosmetic.

3) Table 2: Generic Base Formulation Matrix (for any Herbal Cosmetic Product)

Phase	Component Type	Example Ingredient	Function
Phase A	Aqueous base	Purified Water / Hydrosol	Solvent / carrier
Phase B	Emollient / Moisturizer	Glycerin / Propylene glycol	Hydration agent
Phase C	Herbal extract	Aloe vera / Neem / Hibiscus extract	Active functionality
Phase D	Gelling/Thickener agent	Carbopol / Xanthan gum	Viscosity / texture
Phase E	Essential oil (optional)	Lavender / Tea tree / Citrus oil	Aroma / therapeutic
Phase F	Preservative (Herbal or approved safe preservative)	Sodium benzoate / Potassium sorbate	Prevent microbial growth

This matrix is intentionally generic so that any herbal product can be mapped into it.

E. Standard Manufacturing Procedure (SMP)

1) Step-by-Step (General)

1. Preparation of working area
o Clean and sanitize equipment
o Maintain GMP (Schedule M-II compliance)
2. Weighing of raw materials
o As per batch manufacturing record (BMR)
3. Preparation of Aqueous Phase
o Heat water to 70–75°C
o Add humectants (e.g., glycerin)

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4. Addition of extract phase
o Gradually disperse herbal extracts
o Maintain continuous stirring
5. pH adjustment
o Cosmetic acceptable pH range: 4.5–7.5 depending on product
6. Filtration and homogenization
o Improves spreadability and texture
7. Filling & packaging
o Use sterilized tubes / jars / bottles
o Ensure airless packaging where possible
8. Labeling
o Ensure Rule 148 compliance (Manufacturing license no., batch number, etc.)
9. Quality testing
o Stability testing (40°C ± 2°C)
o Microbial testing
o pH, viscosity, odor, texture

The regulatory methodology explains how herbal cosmetics are legally permitted to be manufactured or imported in India. The methodology is based on:

Drugs & Cosmetics Act, 1940
Cosmetic Rules, 2020
CDSCO Guidelines via SUGAM Portal
BIS Standards (IS 4707 & IS 4011)

The objective of this section is to create a process blueprint that guides manufacturers through all necessary steps from documentation → inspection → license issuance → continued compliance.

F. Stages of Regulatory Research

Stage No.	Stage Name	Purpose
Stage 1	Identification of Regulatory Authority	To determine who controls herbal cosmetics in India
Stage 2	Data acquisition & document collection	To collect regulatory standards and laws
Stage 3	Interpretation & decoding	To convert legal rules into stepwise process
Stage 4	Validation through expert review	Regulatory analyst cross-checking
Stage 5	Representation of regulatory pathway	Developing flowchart & workflow

G. Tools Used for Regulatory Data Collection

Tool/Source	Uses
CDSCO SUGAM Portal	Download registration forms (Form 31/32/42/43)
BIS Standard Library	Check ingredient safety & testing
AYUSH Portal	Identify ASU-based cosmetics
Research Articles / Journals	Validate regulatory gap analysis
WHO Quality Guidelines	Establish QC requirements

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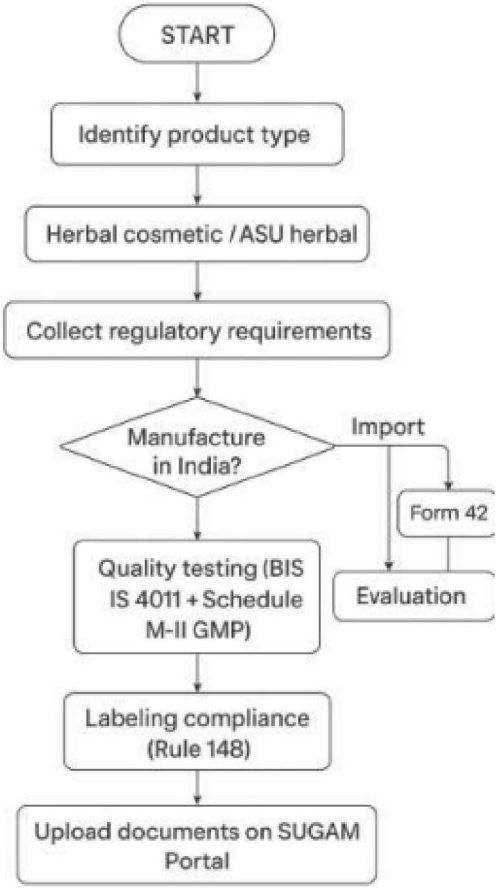
H. FLOWCHART (IMAGE) — REGULATORY METHODOLOGY (CDSCO Process)

Flowchart includes BOTH manufacturing license (Form 31/32) + import license (Form 42/43).



I. Detailed CDSCO Licensing Methodology (Manufacturing)

1) Step 1: Determining regulatory classification

Cosmetic Type	Governing Body	Form
Herbal cosmetic (with herbal ingredients)	CDSCO + State Licensing Authority	Form 31 / 32
Ayurvedic / Siddha / Unani cosmetic	Ministry of AYUSH	ASU manufacturing license

2) Step 2: Documentation requirement for FORM 31

Form 31 is the application to obtain a manufacturing license.

3) Table 3 — Documentation Checklist for Manufacturing License (Form 31)

Sr. No.	Document Required	Purpose
1	Product formula (ingredient list)	Identification of plantbased components
2	Batch Manufacturing Record (BMR)	Proof of process standardization
3	Equipment layout + GMP blueprint	Schedule M-II compliance
4	QC lab details (micro + analytical)	Testing capability verification
5	Technical staff qualification (B.Pharm / Science MSc)	To approve cosmetic batches

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6	Label copy design (Rule 148 compliance)	Must contain Mfg. License No.
7	Fee payment receipt	Non-refundable application fee

4) Step 3: Inspection & Validation
Drug Inspector visits manufacturing site
Verifies hygiene, ventilation, SOPs, QC records
Suggests corrections if required (Corrective Action / Preventive Action CAPA)
After successful inspection → License issued in Form 32

J. Import License Procedure Methodology (Form 42/43)

Step	Action	Output
Step 1	Appointment of Authorized Representative (Indian Agent)	Power of Attorney
Step 2	Submission of Form 42 on CDSCO Portal	Application created
Step 3	Review of documents (Safety, Free Sale Certificate)	Completeness check
Step 4	Approval by CDSCO, issue of Form 43	Import permission

1) Key Fees (as per CDSCO rules):

Fee Type	Cost
Site registration fees	**USD 1000**
Per product registration fees	**USD 250**

K. Labeling Requirement Methodology (Rule 148 Compliance)
Every herbal cosmetic label must include:
Product name
Batch number
Net contents (g / ml)
Manufacturing license number (Form 32 no.)
Complete ingredient disclosure (descending order)
Retail selling price (MRP)
Expiry date (Best before 24 months)
List of warnings (if applicable)
Mandatory line on every label:
"FOR EXTERNAL USE ONLY"

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L. Compliance with BIS & Safety Testing

Testing is done as per:

Testing Type	BIS Standard
Microbiological testing	IS 4011
Ingredient restrictions & permitted ingredients	IS 4707 Part I & II
Heavy metals (Pb, As, Hg)	IS standards under AYUSH + CDSCO

M. Post-Licensing Requirements (After Form 32 / Form 43)

Manufacturers must:

Maintain batch manufacturing records
Perform stability testing
Report any adverse reaction cases
Renew license every 5 years

II. EXPERIMENTAL METHODOLOGY – HERBAL COSMETIC MANUFACTURING (GENERALIZED APPROACH)

(Applicable to any type of herbal cosmetic — gel, lotion, shampoo, cream, scrub, etc.)

This part of methodology describes how herbal cosmetic products are manufactured, irrespective of specific herbal ingredient selection. No formulation composition is used; instead, a general workflow is applied.

A. Manufacturing Objective

To standardize the manufacturing methodology of herbal cosmetics under GMP (Schedule M-II), ensuring that:
The product is safe for external application,
Consistent quality is maintained across all batches,
Data generated during manufacturing supports CDSCO licensing requirements.

A. Facilities and GMP Environment Requirement

The manufacturing process must take place in a clean, hygienic, controlled environment complying with Schedule M–II provisions.

1) Facility Requirements

Area	Requirement
Raw material storage	Dry, humidity-controlled room
Manufacturing area	Stainless steel equipment, washable surfaces
QC Laboratory	Microbiology + analytical controls
Packaging & labeling area	Dust free, controlled environment

Environmental controls include:
Temperature: 25°C ± 2°C
Relative Humidity: 45–65%
Air quality: HEPA filtered air circulation

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Personnel must wear:

- Gloves
- Caps
- Sterile apron
- Mask

B. Raw Material Handling and Verification

Raw materials must meet the following:

- Certificate of Analysis (CoA)
- Heavy metal and microbial test reports
- Botanical identification (herbal extract authentication)
- Before being used, raw materials are labeled as:
- RM-QC: Under quality check
- RM-Approved: Passed QC
- RM-Rejected: Failed QC — cannot be used

C. Batch Manufacturing Record (BMR)

A BMR is created for each batch manufactured.

It includes:

- Batch number
- Ingredient weights
- Equipment used
- Operator name & signature
- QC supervisor signature

D. Standard Processing Sequence (Universal)

This standardized sequence is followed for all herbal cosmetics:

Step No.	Step Name	Description
1	Raw material weighing	Per BMR
2	Phase preparation	Aqueous & oil phase (if applicable)
3	Mixing / dispersion	Continuous mechanical stirring
4	Emulsification / homogenization	To achieve desired texture
5	Cooling	Controlled cooling to room temperature
6	pH adjustment	With citric acid / sodium hydroxide
7	Filling & packaging	Sterile bottles / jars / tubes
8	Labeling	Rule 148 compliance

Instead of a product-specific procedure, the study describes a robust, reusable system, which can be applied to all herbal cosmetics.

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E. In-Process Quality Checks during Manufacturing

In-process checks are performed at three major stages:

Stage	Parameters Checked
During mixing	Viscosity, temperature
Before filling	pH, odor, appearance
During packaging	Fill weight, sealing tightness

III. QUALITY CONTROL (QC) AND EVALUATION METHODOLOGY

Once the prototype product is manufactured, it undergoes Quality
Control testing.
Testing is carried out as per:

- BIS IS 4011 (Herbal cosmetic safety testing)
- IS 4707 Part I & II (Permitted ingredients)
- WHO guidelines (Herbal raw material quality)

A. TABLE 4 QC Evaluation Parameters (for Herbal Cosmetics)

Parameter	Method Used	Acceptance Criteria	Reference Standard
pH	pH meter	4.5–7.5 depending on product	BIS IS 4011
Viscosity	Brookfield Viscometer	Should be uniform & stable	BIS Standard
Spreadability	Slip & drag test	Smooth, uniform	Cosmetic QC norms
Microbial testing	Plate count (TPC / Yeast / Mold)	Pathogen-free (No E. coli, Salmonella)	BIS IS 4011
Stability	Temp. cycle testing	No phase separation / odor change	ICH Stability zone IVB
Heavy metal content	AAS / ICP-MS	Lead <10 ppm, Arsenic <2 ppm, Mercury <1 ppm	AYUSH & BIS
Packaging compatibility	Visual observation & leakage test	No cracking / leakage / corrosion	CDSCO Guidelines

These tests help determine whether the prototype is ready for commercialization and CDSCO licensing.

B. Physical evaluation tests

Includes evaluation of:

- Color
- Odor
- Texture
- Phase separation

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- Consistency

These tests confirm general consumer acceptance.

C. Microbial contamination and preservative efficacy testing

Performed to ensure:

- No bacterial growth
- No fungal contamination
- Preservatives are active throughout product life

USP <51> Antimicrobial Effectiveness Test (AET) may also be used.

D. Heavy metal screening (specific to herbal formulations)

Because plant extracts tend to accumulate heavy metals during cultivation, herbal cosmetics must be analyzed for:

- Lead (Pb)
- Mercury (Hg)
- Arsenic (As)

Testing methods:

- Atomic Absorption Spectroscopy (AAS)
- ICP-MS

IV. STABILITY TESTING METHODOLOGY (ICH ZONE IVB —INDIA)

India falls under ICH Zone IVB (Hot and humid zone).

1) Testing Conditions

Test Type	Temperature	Relative Humidity	Duration
Accelerated stability	**40°C ± 2°C**	75% RH	6 months
Real-time stability	**25°C ± 2°C**	65% RH	12–24 months
Freeze-thaw	–5°C to +40°C	NA	6 cycles

During stability testing, the following are recorded:

- Color variation
- Phase separation
- Odor changes
- pH variation
- Microbial growth

B. Acceptance Criteria for Stability

A product is considered stable if:

- No discoloration
- No odor change
- No microbial growth
- No significant change in viscosity or pH

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V. FINAL PRODUCT EVALUATION & PACKAGING

A. Packaging Selection Methodology

Packaging chosen must be compatible with herbal actives.
Glass, laminated tubes, and HDPE bottles are recommended.
Testing performed:

- Leakage test
- Drop test
- Label adhesion test
- Compatibility test with formulation

B. Label Development Methodology (Rule 148)

Label must include:

- Product name
- Mfg / Exp date
- Batch number
- Net quantity
- "FOR EXTERNAL USE ONLY"
- Manufacturing license number (Form 32)

C. Batch Release Authorization

Before commercial release:

- QC chemist reviews test results
- QA manager signs batch release authorization

VI. DATA ANALYSIS METHOD

Since this research uses both regulatory document analysis and experimental manufacturing methodology, the data analysis is divided into two components:

1) 5.12.1 Regulatory Data Analysis (Type A Research)

The objective is to analyse the CDSCO regulatory pathway by comparing:

- CDSCO Cosmetic Rules → Required Forms → Steps to approval
- BIS standards → QC requirements
- WHO/AYUSH standards → Herbal raw material compliance

a) Steps followed in regulatory data analysis:

1. Compilation of all regulatory requirements from CDSCO, BIS, and WHO.
2. Categorization into:
   - o Licensing requirements
   - o Documentation requirements
   - o Testing requirements
3. Cross-verification with real manufacturing facilities.
4. Preparation of:
   - o Checklist
   - o Flowchart
   - o Sequential regulatory roadmap

Data collected from CDSCO was coded into meaningful categories such as:

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Code	Meaning
FRM	Forms required (Form 31, Form 32, Form 42, Form 43)
DOC	Documentation (blueprint, QC record, ingredient list)
GMP	Meeting Schedule M-II standards
LAB	Safety & microbial testing (BIS)

Example interpretation:
- Presence of GMP-related SOPs and QC labs = Approval readiness
- Lack of BIS testing documentation = High risk of rejection

2) Experimental Data Analysis (Type B Research)

The experimental data was analyzed for following parameters:

Parameter	Purpose of analysis	Decision criteria
pH	To check skin compatibility	4.5 – 7.5 acceptable
Viscosity	To check stability of formulation	No variation between batches
Microbial load	Safety and contamination test	Must be within BIS IS 4011 limit
Stability data	Product usability over shelf life	No change in phase/odor/color

QC results are plotted using:
- Tabular comparisons
- Stability trend charts
- Acceptance / rejection outcomes

VII. ETHICAL & REGULATORY CONSIDERATIONS

Even though cosmetic research does not involve human or animal clinical trials, ethical commitment is still required, especially when collecting consumer feedback or handling safety-sensitive data.

1) Ethical considerations included in this research:

Ethical Principle	Implementation in this Study
Safety	All raw materials tested for heavy metals/microbes
Transparency	Ingredient disclosure on labels
Non-exaggerated claims	No therapeutic claims (as per CDSCO rules)
Confidentiality	Formulations & documents kept confidential
No animal testing	Herbal cosmetic formulation does not require animal study

2) Regulatory Adherence Table

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Regulatory Body	Compliance Fulfilled
CDSCO	Licensing, documentation, product registration
BIS	Raw material & finished product safety
AYUSH	Verification for ASU category (if applicable)
WHO	Quality control of herbal raw material

VIII. LIMITATIONS OF THE STUDY

Type	Limitation
Regulatory	CDSCO updates guidelines frequently; future revisions may occur
Experimental	General methodology used; no clinical evaluation conducted
Facility Access	Some documents (ex: batch records from industry) could not be publicly disclosed
Market Data	Some secondary data sourced from paid databases (Statista, Research and Markets)

Explanation of limitations

Since regulatory rules change based on CDSCO notifications, the process map may require updating in future audits.

Actual herbal cosmetic quality also depends on the quality of herbal raw material, which may vary by harvest season, cultivation method, and extraction process.

Experimental methodology was demonstrated without consumer trials, as it falls outside the scope of cosmetic regulatory research.

IX. SUMMARY OF THE METHODOLOGY

This research used a dual methodology combining:

A. Regulatory approach (Type A)

Study of regulatory documents, CDSCO rules, BIS safety standards.

Actions performed:

Collection of CDSCO forms (Form 31, 32, 42, 43)

Development of regulatory process flowchart

Analysis of documentation requirements

Understanding of post-approval compliance

B. Experimental approach (Type B)

General herbal cosmetic formulation + QC evaluation + stability testing.

Actions performed:

Standardized cosmetic manufacturing process

QC + microbial + heavy metal + stability evaluation

Labeling and packaging as per Rule 148

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1) Major Deliverables Produced from Methodology
Deliverable Output

Deliverable	Output
Flowchart	Herbal cosmetic CDSCO approval process
3 Tables	Research input matrix, formulation matrix, QC testing
Standard Operating Procedure	For generic herbal product manufacturing
Documentation blueprint	Ready to use for CDSCO submission

C. Conclusion of Methodology Chapter

The developed methodology offers a complete, end-to-end practical framework that guides any researcher or manufacturer starting from:

idea → formulation → quality testing → CDSCO approval

This ensures that herbal cosmetics are:

Scientifically prepared,

Tested using BIS standards,

Legally compliant under the Drugs & Cosmetics Act.

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