Application and Evaluation of new cosmetic ingredients guide

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Cosmetics raw materials on the issuance of new guidelines for the review of the notification and reporting

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Provinces, autonomous regions and municipalities Food and Drug Administration (Drug Administration), the unit:

New cosmetic ingredients to enhance the administrative licensing work to ensure quality and safety of cosmetic products, based on "cosmetics Health Supervision" and its Implementing Rules and other relevant provisions of the State Food and Drug Administration to develop a "declaration of new cosmetic raw materials and guidelines for the review." Is hereby issued, please comply.

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State Food and Drug Administration

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Attachment:

Application and Evaluation of new cosmetic ingredients guide

This guide is intended to guide the declaration of new cosmetic ingredients and review.

First, the definition of new cosmetic ingredients

New cosmetic raw material is used in cosmetics in the country for the first time the production of natural or artificial materials.

Second, the security requirements of new cosmetic ingredients

New cosmetic ingredients in the normal and reasonable foreseeable conditions of use shall not cause harm to human health.

Toxicological evaluation of new information on cosmetic ingredients should include toxicological safety evaluation review, the necessary toxicology testing information security risks and possible materials for safety assessment data.

Cosmetics raw materials are generally in need of new toxicology tests following:

(A) acute oral and acute dermal toxicity test;

(B) the skin and acute eye irritation / corrosion test;

(C) the skin allergy test;

(D) and light-sensitive skin phototoxicity test (UV absorption properties of raw materials has to be done when the trial);

(E) mutation test (should at least include a gene mutation test and a chromosome aberration test);

(F) sub-chronic oral and dermal toxicity test;

(G) teratogenic test;

(H) chronic toxicity / carcinogenicity test combination;

(Ix) toxicokinetics and dynamics test;

(X) according to the characteristics and use of raw materials, but also consider other necessary tests. If the new material has been used in cosmetics and chemical structure and properties of similar materials, you can consider reducing some of the test.

This guide provides information for the principle requirements of toxicology tests, according to the physical and chemical properties of raw materials, QSAR, toxicology, clinical research, epidemiology and population similar to the toxicity of compounds, such as information a pilot project to increase or reduce .

Third, new cosmetic ingredients administrative licensing requirements for disclosure of information

Apply for new cosmetic ingredients cosmetic administrative license shall accept the administrative licensing requirements to submit information returns. Specific requirements are as follows:

(A) new cosmetic raw materials, administrative licensing application form

(B) development report

1 Materials R & D background, process and related technical information.

(2) the name of raw material, origin, molecular weight, molecular formula, chemical structure, physical and chemical properties.

(1) Name: raw materials, including the chemical name (IUPAC name and / or CAS name), INCI name and their Chinese translation, trade names and CAS numbers. Material should also indicate the name of the use of raw materials specifications.

Natural raw materials should also provide the Latin scientific name.

(2) Source: raw materials should not be a compound formed in the material due to unavoidable technical reasons, the existence of solvents, stabilizers, carriers, etc., except.

Natural materials should be a single source, and provides the use of parts and so on. All plants have been allowed to be used as cosmetic raw materials, not all parts of the plant material and then a new declaration.

(3) molecular weight, molecular formula, chemical structure: chemical structure should provide the basis for confirmation (eg, NMR, elemental analysis, mass spectrometry, infrared spectra, etc.) and analytical results, should also provide polymer relative to the average molecular weight and its distribution.

(4) physical and chemical properties include: color, odor, state, solubility, melting point, boiling point, specific gravity, vapor pressure, pH value, pKa value, refractive index, optical rotation and so on.

3 ingredients in cosmetics intended use, scope of use for security and the use of limited basis, cautions, warnings, etc.

4 ingredients in a foreign country (region) is used in cosmetics case descriptions.

(C) the production process description and diagram

Should indicate the new cosmetic raw materials to produce the major steps involved in the process, procedures and parameters, such as raw materials should be listed, the reaction conditions (temperature, pressure, etc.), additives (catalysts, stabilizers), intermediates and by-products and the preparation steps etc.; the case of natural extracts, should indicate the processing, extraction method, extraction conditions, the use of solvents, may be residual impurities or solvent.

(D) raw material quality and safety control requirements

Should include specifications, test methods, there may be a security risk substances and control measures and so on.

1. Specifications include: purity or content of impurity species and their respective content (residual monomer and polymer content to be described) and other indicators of quality and safety control, due to unavoidable technical reasons exist in the raw materials of solvent, stabilizer, carrier, etc. types and their respective content, other physical and chemical parameters, shelf life and storage conditions; the case of natural plant extracts, should be clear indicators of its quality and safety control.

2 detection methods: qualitative and quantitative material testing methods, testing methods impurities.

3 possible security risk substances and their control measures.

(E) toxicological safety evaluation data (including raw materials, there may be security risks in the safety assessment of material information)

Toxicology test data can be the applicant's test data, scientific literature and domestic and foreign government official website, the content of websites of international organizations.

1 apply for new cosmetic ingredients, cosmetics, new materials generally should be required to submit safety data toxicology tests.

(2) one of the following circumstances, according to the following requirements to submit toxicology test data. According to the characteristics and use of raw materials, if necessary, may request an increase or reduction related to experimental data.

(1) who do not have preservatives, sunscreens, colorants and dyes, and functional ingredients from a safety point of view not included in the "Hygienic Standard for Cosmetics" Restricted substances tables new cosmetic raw materials, should submit the following information:

1) The acute oral and acute dermal toxicity test;

2) skin and acute eye irritation / corrosion test;

3) skin allergy test;

4) and light-sensitive skin phototoxicity test (UV absorption properties of raw materials has to be done when the two trials);

5) mutation test (should at least include a gene mutation test and a chromosome aberration test);

6) sub-chronic oral or dermal toxicity test. If the raw materials used in cosmetics, the possibility of oral intake of large,

should provide sub-chronic oral toxicity test.

(2) comply with the conditions (1), and by foreign (regional) authorities on cosmetic ingredients catalog reproduces more than four years, involves no harm to human health may be related to literature, should submit the following information:

1) The acute oral and acute dermal toxicity test;

2) skin and acute eye irritation / corrosion test;

3) skin allergy test;

4) and light-sensitive skin phototoxicity test (UV absorption properties of raw materials has to be done when the two trials);

5) mutation test (should at least include a gene mutation test and a chromosome aberration test).

(3) Where a history of safe human consumption, such as domestic and foreign government official or agency or authority issued by the safety assessment of food ingredients considered safe and its extracts, the State Council administrative department announced as both food and pharmaceutical items, etc. should submit the following information:

1) skin and acute eye irritation / corrosion test;

2) The skin allergy test;

3) and light-sensitive skin phototoxicity test (UV absorption properties of raw materials has to be done when the trial).

(4) by one or more structural units connected by covalent bonds, relative to the average molecular weight greater than 1000 daltons new polymers as cosmetic raw materials, should submit the following information:

1) skin and acute eye irritation / corrosion test;

2) skin phototoxicity test (UV absorption properties of raw materials has to be done when the trial).

(5) Where a foreign (regional) authorities evaluation concluded that it is safe to use in cosmetics of the new material, reporting is not required to provide toxicological test data, but should be submitted to foreign countries (regions) to assess the conclusions of evaluation reports and related information. Foreign (region) approved a new cosmetic ingredients, should be submitted to the approval certificate.

(F) imports new cosmetic raw materials, the applicant shall be submitted to the administrative licensing has been filed to declare the responsible units in China, power of attorney and a copy of their reporting responsibilities on the administrative licensing unit in China business license and official seal.

(G) may contribute to the administrative licensing and other information.

Applicants should be based on the new material properties according to the above requested information, unless the relevant requirements do not apply.

Attached a sample sent for screening.

Fourth, the principle of new cosmetic ingredients review

(A) for the applicant to submit the safety evaluation of new cosmetic ingredients data integrity, reasonable and

scientific conduct of the review:

1 safety evaluation of information content is complete and consistent information requirements;

2 based on whether the scientific, critical data is reasonable, analysis is logical, conclusion is correct;

3 key new source of raw materials of cosmetics review, physical and chemical nature, purpose, scope, and limited use basis, production processes, quality and safety control requirements and the necessary toxicological evaluation of information.

(B) The review considered cosmetic safety evaluation of new raw material problems, the experts should review the relevant provisions of cosmetics regulatory and scientific basis, to make specific comments. The applicant within the prescribed time limit should provide appropriate safety evaluation.

(C) With the development of scientific research, the State Food and Drug Administration has approved cosmetics can re-evaluation of new materials.

Fifth, a special type of reporting and review of new cosmetic raw material requirements will be forthcoming.

VI Abbreviations

(A) IUPAC, International Union of Pure and Applied Chemistry (International Union of Pure and Applied Chemistry) abbreviations.

(B) CAS, the American Chemical Abstracts Service (Chemical Abstracts Service) abbreviations.

(C) INCI, International cosmetic ingredients named (International Nomenclature Cosmetic Ingredient) abbreviation.

This guide by the State Food and Drug Administration responsible for the interpretation.

This guide is from July 1, 2011 shall come into force. Previously published report and review of new cosmetic ingredients regulations inconsistent with this guide in order to prevail in this guide.

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