COSMETIC INGREDIENT REVIEW
PROCEDURES'

Part A—General

Section 1. Definitions. (a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) "Cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that it shall not include soap.

(c) "Cosmetic ingredient" means any chemical substance used as a component in the manufacture of a cosmetic product, but shall not include a proprietary mixture.

(d) "Cosmetic product" means a finished cosmetic the manufacture of which has been completed.

(e) "Commercial distribution" of a cosmetic product means annual gross sales in excess of $1,000 for the product.

(f) "Chemical description" means a concise definition of the chemical composition using standard chemical nomenclature so that the chemical structure or structures of the components of the ingredient would be clear to a practicing chemist. When the composition cannot be described chemically, the substance shall be described in terms of its source and processing.

(g) "Flavor" means any natural or synthetic substance or substances used solely to impart a taste to a cosmetic product.

(h) "Fragrance" means any natural or synthetic substance or substances used solely to impart an odor to a cosmetic product.

(i) "Cosmetic Ingredient Review" means the Cosmetic Ingredient Review program conducted pursuant to these procedures.

(j) "CTFA" means The Cosmetic, Toiletry and Fragrance Association, Inc.

(k) "Director" means the Director of the Cosmetic Ingredient Review, who shall have the authority and responsibilities established in Section 12 of these procedures.

(l) "Administrator" means the Administrator of the Cosmetic Ingredient Review, who shall have the authority and responsibilities established in Section 13 of these procedures.

(m) "Scientific Coordinator" means the Scientific Coordinator of the Cosmetic Ingredient Review, who shall also be the Executive Secretary of the Expert Panel, who shall have the authority and responsibilities established in Section 14 of these procedures.

Includes amendments approved by CIR Steering Committee and CTFA Board of Directors as of February 25, 1979.

Old Sections 43-45 renumbered as 44-46; new Section 43 added.
(n) “Expert Panel” means the Cosmetic Ingredient Review Expert Panel, which shall be established and shall have the authority and responsibilities established in Part C of these procedures and shall conduct the Cosmetic Ingredient Review program in accordance with the procedures established in Part D of these procedures.

(o) “Executive Secretary” means the Executive Secretary of the Expert Panel, who shall be the Scientific Coordinator and shall have the authority and responsibilities established in Section 14 of these procedures.

(p) “Safe” or “safety” means no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public under the conditions of use that are now current or that might reasonably be expected in the future, e.g., a low incidence of minor adverse reactions (as shown in animal or human testing or product experience). Such information includes, but is not limited to, the chemical structure of the ingredient, published and unpublished tests on the ingredient and products containing the ingredient, significant human experience on products containing the ingredient during marketing, and information on similar or related substances. A lack of information about an ingredient shall not be sufficient to justify a determination of safety.

(q) “Conditions of use” for an ingredient or product include (1) the amount of an ingredient used in a product, (2) the intended and reasonably foreseeable areas of use (e.g., use that is subject to ingestion or inhalation or contact with mucous membranes or is in the area of the eye), and (3) directions for use and against misuse in labeling.

Section 2. Purpose of the Cosmetic Ingredient Review. The purpose of the Cosmetic Ingredient Review is to determine those cosmetic ingredients for which there is a reasonable certainty in the judgment of competent scientists that the ingredient is safe under its conditions of use.

Section 3. Interpretation and Amendment of Procedures. (a) If any dispute arises as to the proper interpretation or application of these procedures, a majority vote of the Steering Committee shall be final and binding with respect to such matter.

(b) These procedures may be amended by a two-thirds vote of the Steering Committee, with the approval of the CTFA Board of Directors. The Administrator shall give public notice of any amendment of these procedures.

Part B—The Cosmetic Ingredient Review Steering Committee and Staff

Section 10. Organization of the Cosmetic Ingredient Review. (a) General policy and direction for the Cosmetic Ingredient Review shall be given by a Steering Committee. A quorum of the Steering Committee shall consist of three members. Any matter before the Steering Committee shall be decided by a majority vote of the members present at the time except where otherwise specifically provided in these procedures. The Steering Committee shall consist of the following members:

(1) The President of CTFA, who shall serve as the Chairman of the Steering Committee.
(2) A dermatologist, who shall represent the American Academy of Dermatology.
(3) A toxicologist, who shall represent the Society of Toxicology.
(4) The Chairman of the CTFA Scientific Advisory Committee.
(5) The CTFA Vice President for Science.

(b) The Cosmetic Ingredient Review staff shall consist of a Director, who shall report to the Cosmetic Ingredient Review Steering Committee, and the Administrator and the Scientific Coordinator, who shall report to the Director. The Director, Administrator, and Scientific Coordinator may in turn utilize such other personnel as is necessary and appropriate to carry out their authority and responsibilities established in Sections 12-14 of these procedures.

Section 11. Separation and Independence of the Cosmetic Ingredient Review Staff from the CTFA Staff. (a) The Cosmetic Ingredient Review staff shall be employees of or consultants to CTFA but shall be separate and independent from the CTFA staff. No person on the Cosmetic Ingredient Review staff may also serve on the CTFA staff. The Cosmetic Ingredient Review staff may obtain supplies and services through the central facilities of CTFA. Contact between the Cosmetic Ingredient Review staff and the CTFA staff shall be kept to the minimum necessary to conduct the affairs of the Cosmetic Ingredient Review efficiently and effectively. CTFA staff shall be treated by the Cosmetic Ingredient Review staff the same as any other member of the public (e.g., all CTFA staff shall sign the visitors log when visiting the Cosmetic Ingredient Review offices).

(b) The Cosmetic Ingredient Review staff shall follow all personnel policies and procedures established in the CTFA Procedures Manual, except that the Director shall be responsible for all required approvals within the authority granted to him under Section 12 of these procedures.

Section 12. Director. (a) The Director shall be appointed by the CTFA President, with the approval of the Chairman of the CTFA Board of Directors and the Chairman of the CTFA Scientific Advisory Committee.

(b) The Director shall hire and direct the activities of the Cosmetic Ingredient Review staff in order to implement these procedures effectively and efficiently. The Director shall report to and be subject to the direction and control of the Steering Committee with respect to policy and budget within the following limitations:

(1) The CTFA Board of Directors shall determine the budget and personnel limits for the Cosmetic Ingredient Review.

(2) The Steering Committee shall periodically review all Cosmetic Ingredient Review expenditures (e.g., document reproduction, communications, accounting, and office space expenditures) to determine that they are within the budget.

(3) All Cosmetic Ingredient Review contracts and capital expenditures shall be reviewed and approved by the Steering Committee prior to execution.

(4) All Cosmetic Ingredient Review office supplies shall be obtained through CTFA central purchasing unless otherwise approved by the Steering Committee.
(c) The Administrator or Scientific Coordinator may simultaneously serve as the Acting Director in the absence of the Director, or as the Director.

**Section 13. Administrator.** The Administrator, under the direction of the Director, shall have authority and responsibility for daily administration of the Cosmetic Ingredient Review staff and Expert Panel. This shall include receipt of all documents submitted by any interested person with respect to the Cosmetic Ingredient Review, distribution of all data and information to the Expert Panel, arranging for all aspects of the meetings of the Expert Panel, including public notice thereof, serving as secretary to the Steering Committee, and all similar administrative functions.

**Section 14. Scientific Coordinator.** The Scientific Coordinator, under the direction of the Director, shall have authority and responsibility to perform all of the scientific functions of the Cosmetic Ingredient Review staff (including, but not limited to, the information science function and obtaining all necessary Scientific Literature Reviews) and of the Expert Panel (including, but not limited to, preparing minutes of all meetings, drafting scientific position papers, and otherwise serving as Executive Secretary to the Expert Panel).

**Part C—The Cosmetic Ingredient Review Expert Panel and Liaison Representatives**

**Section 20. Members of the Expert Panel and Liaison Representatives.** (a) Members of the Expert Panel shall possess the following qualifications:

(1) Members shall possess expertise relevant to the review of the safety of cosmetic ingredients. They shall have diverse professional education, training, and experience so that the Expert Panel will reflect a balanced composition of sufficient scientific expertise to handle the issues that come before it.

(2) Members shall be required to meet the same conflict of interest standards as are applicable under Federal law to special government employees.

(3) Liaison representatives shall be selected by the interested organizations as provided in Section 22 of these procedures. Technical expertise with the subject matter with which the Expert Panel is involved shall not be a requirement.

(b) Members appointed to the Expert Panel and liaison representatives shall continue to serve for the duration of the Expert Panel or until they resign or are removed from membership for cause by the Steering Committee.

(c) An Expert Panel member may be removed from membership by the Steering Committee for good cause. Good cause shall include but not be limited to excessive absenteeism from Expert Panel meetings, a demonstrated bias which interferes with the ability to render objective advice, or failure to abide by these procedures.

(d) There shall ordinarily be seven members of the Expert Panel, each member having an equal vote. The Expert Panel shall begin to function, and may continue to function, as long as there are not less than five members.

**Section 21. Nominations and Selection of Members of the Expert Panel.** (a) The Administrator shall give public notice requesting nominations for
members of the Expert Panel. The notice shall invite the submission of nominations for members from any interested individual as well as from consumer, industry, and professional organizations, within 90 days of such notice.

(b) Any interested person may nominate one or more qualified person(s) as a member of the Expert Panel. Nominations shall include a complete curriculum vitae of the nominee, and shall state that the nominee is aware of the nomination, is willing to serve as a member of the Expert Panel, and appears to have no conflict of interest which would preclude membership on the Expert Panel.

(c) Members of the Expert Panel shall serve as individuals and not as representatives of any group or organization which nominated them or with which they may be affiliated.

(d) The Steering Committee shall appoint the members of the Expert Panel from among those who have been nominated. Appointment shall be decided by a four-fifths vote of all current members of the Steering Committee. Appointment shall be on the basis of scientific competence, expertise in an area relevant to the Cosmetic Ingredient Review, balance of scientific disciplines within the Expert Panel, willingness to devote sufficient time and energy to the review, and the lack of any disqualifying conflict of interest.

(e) All data and information relating to the nomination and selection of the members of the Expert Panel shall be maintained by the Administrator in a confidential file.

(f) Vacancies in the membership of the Expert Panel shall be filled by the Steering Committee either from prior nominations or in the same way that members are initially nominated and selected.

Section 22. Selection of Liaison Representatives to the Expert Panel. (a) The Administrator shall request that each of the following interests designate a liaison representative to the Expert Panel:

(1) The Food and Drug Administration, in accordance with the provisions of proposed 21 C.F.R. 2.21(d).

(2) Organizations representing consumer interests.

(3) CTFA.

(b) Liaison representatives to the Expert Panel shall be limited to three persons, one representing each of the listed interests. Those interests may, however, designate different liaison representatives for purposes of the review of different categories of cosmetic ingredients or similar considerations. At no time may there be more than one liaison representative to the Expert Panel from any one of the interests listed in Section 22(a) of these procedures with respect to any specific cosmetic ingredient.

(c) Because liaison representatives for government, consumer, and industry interests have no vote, their selection shall be solely by the interests they represent and shall be without regard to the conflict of interest principles for special government employees that are applicable to the members of the Expert Panel.

(d) Vacancies in the liaison representatives to the Expert Panel shall be filled in the same way that liaison representatives are initially selected.
Section 23. Rights and Responsibilities of Liaison Representatives to the Expert Panel. (a) A liaison representative to the Expert Panel selected to represent and serve as a liaison with interested individuals, associations, and organizations, shall have the same rights as members of the Expert Panel except that:

(1) A liaison representative shall not vote on any matter before the Expert Panel.

(2) A liaison representative shall not have access to confidential data and information that are not available for public disclosure pursuant to section 51(b) of these procedures. Accordingly, a liaison representative shall not be present at any portion of an Expert Panel meeting which is closed for the presentation of confidential data pursuant to Section 34(c) or the discussion of confidential data pursuant to Sections 34(d) and 36(b)(2) of these procedures which are prohibited from public disclosure pursuant to Section 51(b) of these procedures.

(b) A liaison representative of the Expert Panel is subject to, and shall abide by, all aspects of these procedures and any rules and regulations adopted by the Expert Panel pursuant to Section 32 of these procedures.

(c) It is the responsibility of the liaison representatives to the Expert Panel to represent the government, consumer, and industry interests in all deliberations.

(1) The consumer and industry liaison representative does not represent any particular organization or group, but rather represents all interested persons within the class which he is selected to represent. Accordingly, any interested person within the class represented by that liaison representative shall have access to all written statements or oral briefings related to the Expert Panel prepared by the liaison representative for distribution to any person outside the Expert Panel.

(2) Liaison representatives shall review all official Expert Panel minutes to assure their completeness and accuracy.

(3) The liaison representative shall act as a liaison with and conduit between the Expert Panel and the interested persons whom he represents, and shall transmit requests for information from the Expert Panel and relevant data, information, and views to the Expert Panel. He shall take the initiative in contacting interested persons whom he represents, to seek out relevant data, information, and views, and to relate the progress of the Expert Panel.

(4) The industry liaison representative shall represent all members of the industry, and not any particular association, company, product, or ingredient. If a matter comes before the Expert Panel that directly or indirectly affects the company which employs the industry liaison representative, he need not absent himself during the discussion or decline to participate in the discussion. The industry liaison representative shall not discuss his company’s position as such, but may discuss any matter in general terms. All presentations and discussions of scientific data and their interpretation on behalf of a company shall occur in open session, except as provided in Section 34(c) of these procedures.

(5) A liaison representative to the Expert Panel shall not make any presentation to the Expert Panel during a hearing conducted by the Expert Panel.
(6) Although a liaison representative is serving in a representative capacity, he shall exercise restraint in performing his functions and shall not engage in unseemly advocacy or attempt to exert undue influence over members of the Expert Panel.

(c) A liaison representative to the Expert Panel may be removed by the Steering Committee for failure to comply with the provisions of this section or the other sections of these procedures. In the event of removal of a liaison representative, the interests which he has represented shall be requested to select a new liaison representative.

**Section 24. Compensation of Expert Panel Members.** (a) All members of the Expert Panel and liaison representatives shall receive a consultant fee of $400 per day and be reimbursed for their travel expenses and all other out-of-pocket expenses, unless such compensation and reimbursement is waived.

(b) An Expert Panel member or liaison representative notwithstanding his primary residence, while in attendance at meetings of the Expert Panel, will be paid whether the meetings are held in his city of residence or elsewhere.

(c) An Expert Panel member or liaison representative who participates in a specific assignment for the Expert Panel, at the request of the Cosmetic Ingredient Review, will be paid at an hourly rate of $50 when he performs his work at home, place of business, or elsewhere, and at a daily rate when he is required to travel outside of his commuting area to perform his assignment. An Expert Panel member or liaison representative will not be paid for time spent on normal preparation for a meeting of the Expert Panel.

(d) Salary while in travel status is authorized when an Expert Panel member or liaison representative has his ordinary pursuits interrupted for the substantial portion of an additional day beyond the day or days on which he performs services, and as a consequence he sustains a loss in his regular compensation. This applies on weekends and holidays if the Expert Panel member or liaison representative suffers a loss in income he would otherwise earn on that day. For travel purposes, a substantial portion of a day is defined as 50 percent of the working day, and the traveller will be paid at a daily rate.

**Section 25. Chairman of the Expert Panel.** (a) The Steering Committee shall select a Temporary Chairman of the Expert Panel from among the members, who shall serve as the Temporary Chairman for the initial organizational meetings. Thereafter, the Expert Panel shall determine its own Chairman from among the members, who may serve on a permanent or on a rotating basis.

(b) The Expert Panel Chairman shall have the authority to conduct hearings and meetings, including the authority to adjourn any hearing or meeting whenever he determines adjournment to be advisable, to discontinue discussion of a particular matter, to conclude the open portion of a meeting in accordance with Section 36 of these procedures, or to take any other action in furtherance of a fair and expeditious hearing or meeting.

**Section 26. Ex Parte Contacts With the Expert Panel.** (a) There shall be no ex parte contacts between the members of the Expert Panel and anyone other than a liaison representative to the Expert Panel or a member of the Cosmetic
Ingredient Review staff with respect to any matter relating to the Cosmetic Ingredient Review, except that:

(1) The Steering Committee may meet with the Expert Panel or any members thereof or any liaison representatives to discuss the work of the Expert Panel.

(2) A member of the Expert Panel may, in his discretion, initiate discussions with any other scientist for the purpose of obtaining data, information, or views with respect to any scientific issue.

(b) If any person initiates an ex parte contact with a member of the Expert Panel other than as permitted by paragraph (a) of this section, such member shall refer such person to the Cosmetic Ingredient Review staff for advice on the procedures for submission of data, information, and views to the Expert Panel.

Section 27. Compilation of Background Materials for Members of the Expert Panel and Liaison Representatives. The Administrator shall prepare and provide to Expert Panel members and liaison representatives a complete compilation of background materials bearing upon their duties and responsibilities.

Part D—The Cosmetic Ingredient Review Procedures

Section 30. Compilation of Safety Data and Information and Review by the Expert Panel. (a) The Steering Committee shall develop a tentative priority list(s) for the systematic review of all cosmetic ingredients presently used in commercially distributed cosmetic products. This tentative priority list(s) shall be based upon the frequency of use (i.e., the number of different products in which an ingredient is used), availability of chemical specifications or descriptions, any known questions about safety, and the availability of sufficient data and information for the Expert Panel to make an informed scientific judgment on safety.

(1) For those cosmetic ingredients for which no particular priority can be established, their priority shall be determined by a statistically reliable randomization.

(2) For those cosmetic ingredients which are also subject to other existing safety reviews, their inclusion and priority shall be determined pursuant to paragraph (i) of this section.

(b) The tentative priority list(s) shall be made publicly available and 90 days will be provided for public comment on it.

(c) The Expert Panel shall review the tentative priority list(s) and all comments received on it, make any revisions it concludes appropriate, and adopt a final priority list(s). The final priority list(s) shall determine the order in which cosmetic ingredients are reviewed under the Cosmetic Ingredient Review. The Expert Panel may at any time revise the final priority list(s) either to add new ingredients or to revise the priority of existing ingredients.

(d) On the basis of the tentative and final priority list(s) the Scientific Coordinator shall develop or obtain Scientific Literature Reviews for each cosmetic ingredient (or, where appropriate, closely related groups of cosmetic ingredients), which shall consist of a bibliography of the domestic and foreign toxicological literature and any other major domestic and foreign scientific
literature, a description of each literature reference, and a summary of the information found for each ingredient.

1. The Scientific Coordinator may either contract for the preparation of each Scientific Literature Review or prepare it himself.

2. As soon as it is available, each Scientific Literature Review will be made public and 90 days will be provided for public comment on it.

3. If the Scientific Coordinator concludes that there is insufficient scientific literature to justify the preparation of a Scientific Literature Review, the Administrator shall give public notice that no Scientific Literature Review will be prepared for the ingredient involved.

(e) Upon the public notice of the availability of a Scientific Literature Review, or that no Scientific Literature Review will be prepared, all interested persons will be provided 90 days to submit to the Administrator data, information, and views relevant to the safety of the cosmetic ingredient involved. A person may submit any particular piece of information without identifying the source of that information. To be considered, twelve copies of the data and views shall be submitted, preferably bound, indexed, and on standard size paper (approximately 8 1/2 by 11 inches). All submissions shall be in the following format:

COSMETIC INGREDIENT REVIEW INFORMATION

I. The CTFA adopted name(s) and tradename(s) of the cosmetic ingredient(s) involved, the name of the manufacturer, and if it does not meet the specifications in any of the information sources designated in the CTFA Cosmetic Ingredient Dictionary a statement to that effect and the specifications that are applicable.

II. Comments, if any, on the completeness and accuracy of the Scientific Literature Review for the ingredient.

III. A statement setting forth the number of products containing the ingredient manufactured or distributed by the person making the submission, and the pertinent letter for each indicating the range of the concentration of the ingredient for each product, as is shown in the information submitted to the Food and Drug Administration on Form FD-2512 (Cosmetic Product Ingredient Statement), 21, C.F.R. 720.4(d) (1).

IV. Animal safety data.

A. All animal safety data not included in the Scientific Literature Review on the individual cosmetic ingredient.

B. All animal safety data not included in the Scientific Literature Review on combinations of the individual cosmetic ingredient.

C. All animal safety data not included in the Scientific Literature Review on cosmetic products or other products containing the individual cosmetic ingredient as one component.

V. Human safety data (including exposure during clinical testing, in occupational settings, and through product use).

A. All human safety data not included in the Scientific Literature Review on the individual cosmetic ingredient.

B. All human safety data not included in the Scientific Literature Review on the individual cosmetic ingredient.
on combinations of the individual cosmetic ingredients.

C. All human safety data not contained in the Scientific Literature Review on cosmetic products or other products containing the individual cosmetic ingredient as one component, including results of significant human experience during marketing. Such data may include relevant Forms FD-2704 (Cosmetic Product Experience Report), FD-2705 (Cosmetic Product Unusual Experience Report), and FD-2706 (Summary Report of Cosmetic Product Experience by Product Categories), 21 C.F.R. Part 730.

VI. Other Relevant Safety Information.

VII. Conditions of use.

A. A statement that the ingredient is or is not used in a cosmetic which falls into the following general use classifications.

1. Eye area use.
2. Subject to incidental ingestion.
3. Subject to incidental inhalation.
5. All other uses (e.g., skin, hair, and nails).

B. A statement indicating the use classifications for each of the products in which the ingredient is used by the manufacturer or distributor, as specified in Food and Drug Administration Form FD-2512 (Cosmetic Product Ingredient Statement), 21 C.F.R. 720.4(c).

C. Information on any other relevant conditions of use (e.g., directions for use and against misuse).

VIII. A summary of the data and views setting forth the rationale for the conclusion that the ingredient is or is not safe for its intended use.

(f) Upon the public notice of the availability of a Scientific Literature Review, CTFA and any other interested person may submit to the Administrator a chemical description of the ingredient involved, if one is available.

(g) Upon expiration of the time permitted for receipt of all of the pertinent data and information, the Scientific Coordinator shall prepare a final compilation of relevant data and information for presentation to the Expert Panel. That compilation shall include:

1. The Scientific Literature Review.
2. All comments received on the Scientific Literature Review.
3. All submissions of data and information not contained in the Scientific Literature Review.
4. All chemical descriptions submitted.

(h) The Expert Panel may, in its discretion, accept late submissions and new data relating to any ingredient at any time prior to its tentative report on that ingredient.

(i) To minimize duplication of effort, the inclusion and priority of cosmetic ingredients which are also subject to other existing safety reviews shall be determined as follows, except that any specific ingredient the review of which would otherwise be deferred shall nonetheless be included at the discretion of the Expert Panel when other chemically related or otherwise conveniently grouped ingredients are considered, and except with respect to any specific ingredient for which the Expert Panel has assigned a special priority for good
cause with the approval of the Steering Committee.

(1) Color Additives. All color additives shall be excluded from the Cosmetic Ingredient Review because their safety is determined under Section 706 of the Act and 21 C.F.R. Parts 8 and 9.

(2) OTC Drug Active Ingredients. The Expert Panel shall defer evaluation of a cosmetic ingredient which is also used as an active ingredient in an OTC drug, and thus is subject to review under the Food and Drug Administration OTC drug review established in 21 C.F.R. Part 330, until after the final monograph for the relevant OTC drug category (or, if there is more than one, the last relevant OTC drug category) is published by the Food and Drug Administration pursuant to 21 C.F.R. 330.10(a) (9) and shall then determine whether all safety information relevant to cosmetic use of the ingredient was available to the OTC drug review and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the OTC drug review. The Expert Panel shall adopt those conclusions of the OTC drug review which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the OTC drug review.

(3) Food Flavors. The Expert Panel shall defer evaluation of a cosmetic flavor ingredient which is also used as a flavor in food, and thus is subject to review under the FASEB-FDA review of flavor ingredients which are GRAS or food additives described in Part II of the Federal Register of July 26, 1973 (38 F.R. 20036 et seq.) and Part II of the Federal Register of September 23, 1974 (39 F.R. 34172 et seq.), until after the final regulation for the ingredient is published by the Food and Drug Administration and shall then determine whether all safety information relevant to cosmetic use of the ingredient was available to the FASEB-FDA review and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the FASEB-FDA review. The Expert Panel shall adopt those conclusions of the FASEB-FDA review which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the FASEB-FDA review.

(4) GRAS Food Ingredients. The Expert Panel shall defer evaluation of a cosmetic ingredient which is also used as an ingredient in a food on the basis that it has been determined to be GRAS or subject to a prior sanction, and thus is subject to review under the FASEB-FDA review described in Part II of the Federal Register for July 26, 1973 (38 F.R. 20036 et seq.) and Part II of the Federal Register for September 23, 1974 (39 F.R. 34172 et seq.), until after the final regulation is promulgated for the ingredient by the Food and Drug Administration and shall then determine whether all safety information relevant to cosmetic use of the ingredient was available to the FASEB-FDA review and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the FASEB-FDA review. The Expert Panel shall adopt those conclusions of the FASEB-FDA review which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the FASEB-FDA review.
(5) Food Additives. In evaluating a cosmetic ingredient which is also used as a food additive, and thus is subject to a food additive regulation promulgated by the Food and Drug Administration in 21 C.F.R. Part 121, the Expert Panel shall review the food additive petition and all related documents which the Food and Drug Administration makes available to determine whether all safety information relevant to cosmetic use of the ingredient was available to the Food and Drug Administration and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the Food and Drug Administration approval of the food additive regulation. The Expert Panel shall adopt those conclusions of the Food and Drug Administration approval which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the Food and Drug Administration approval.

(6) Fragrance Ingredients. All fragrance ingredients shall be excluded from the Cosmetic Ingredient Review because their safety is being determined by the Research Institute for Fragrance Materials (RIFM).

(7) Food and Drug Administration Regulations. All matters which are the subject of a final regulation promulgated by the Food and Drug Administration shall be excluded from the Cosmetic Ingredient Review.

(8) New Drug Applications. In evaluating a cosmetic ingredient which is also used as an inactive or active ingredient in an OTC or prescription drug for which the Food and Drug Administration has at any time approved or permitted to become effective a New Drug Application, the Expert Panel shall review all related documents which the Food and Drug Administration makes available to determine whether all safety information relevant to cosmetic use of the ingredient was available to the Food and Drug Administration and whether the cosmetic use of the ingredient presents any additional safety considerations not adequately covered by the Food and Drug Administration action on the New Drug Application. The Expert Panel shall adopt those conclusions of the Food and Drug Administration action which it concludes adequately cover cosmetic use of the ingredient and shall conduct its own evaluation of those cosmetic uses not adequately covered by the Food and Drug Administration action.

(i) An ingredient shall be reviewed in accordance with the priority assigned to it pursuant to this section.

(1) Upon presentation of all pertinent data and information to the Expert Panel pursuant to paragraph (g) of this section, an ingredient shall be considered to be under review by the Expert Panel. An ingredient shall remain under review by the Expert Panel until the Expert Panel issues a final report on it pursuant to Section 45 of these procedures.

(2) If the Expert Panel concludes that the available data and information are insufficient to determine such ingredient, under each relevant condition of use, as either safe or not safe, it shall decide the type of further data or information required and the time period within which it might reasonably be obtained. Any such decision shall be set forth fully in the minutes of the Expert Panel meeting.

(A) Upon the public availability of the minutes of any such meeting pursuant to Section 51 of these procedures, the Administrator shall give public notice of any such decision.
(B) Within 90 days after such public notice, any interested person may inform the Expert Panel that work adequate and appropriate to resolve the questions raised about the ingredient will be undertaken.

(C) A progress report on any work undertaken pursuant to such a commitment shall be filed with the Cosmetic Ingredient Review every January 1 and July 1 until completion.

(D) If such a commitment is undertaken, the ingredient shall remain under review by the Expert Panel and the Expert Panel shall defer preparation of a tentative report pursuant to Section 44 of these procedures and a final report pursuant to Section 45 of these procedures until completion of the work involved, unless the Expert Panel determines that the work is not being pursued promptly and diligently or that interim results indicate a reasonable likelihood that a health hazard exists.

(E) Upon completion of the work undertaken pursuant to such a commitment, the Expert Panel shall review all available data and information and shall issue a tentative report pursuant to Section 44 of these procedures and a final report pursuant to Section 45 of these procedures.

(3) If the Expert Panel determines pursuant to paragraph (j) (2) of this section that the available data and information are insufficient to determine such ingredient, under any specific condition of use, as either safe or not safe, and no one undertakes the work to obtain the required data and information in accordance with paragraph (j) (2) of this section, the Expert Panel shall determine that there is a lack of information needed to make a determination and insufficient industry interest in the ingredient at that time to justify obtaining the needed information and shall issue a tentative report pursuant to Section 44 of these procedures and a final report pursuant to Section 45 of these procedures.

Section 31. Meetings of the Expert Panel. (a) The Expert Panel will meet as often and for as long as is appropriate to review the data submitted to it and to prepare a report containing its conclusions and recommendations with respect to the safety of cosmetic ingredients.

(b) The Expert Panel shall convene at the call of the Chairman. The Administrator shall be responsible for giving appropriate notice to all Expert Panel members and liaison representatives for distributing all pertinent information, for all travel and meeting arrangements, and for similar administrative support.

(c) All Expert Panel meetings shall be held in Washington, D.C., or the immediate vicinity, unless there are compelling reasons for a different location. A different location may be approved by the Steering Committee for good cause.

(d) The Expert Panel may, with the approval of the Steering Committee, conduct on-site visits relevant to the work of the Expert Panel.

(e) A quorum for the Expert Panel shall be five members of the Expert Panel. Any matter before the Expert Panel shall be decided by a majority vote of the members present at the time, except that any final report shall be voted upon by all current members of the Expert Panel. Any current member of the Expert Panel may file a separate report with additional or minority views.
(f) Subject to availability of space, any interested person may attend any portion of any Expert Panel meeting which is not closed.

(g) Any portion of a meeting shall be closed by the Expert Panel Chairman when matters which have been determined closed in accordance with Section 36 of these procedures are to be discussed. Where a portion of the meeting is closed, the closed portion shall be held after the conclusion of the open portion whenever practicable.

(h) Any Expert Panel member or liaison representative may take notes during Expert Panel meetings and report and discuss the deliberations of the Expert Panel after a meeting is completed and before official minutes or a report is available, within such rules and regulations as are adopted by the Expert Panel in accordance with Section 32 of these procedures.

(1) There shall be no attribution of individual views expressed in a closed session or revealing of numerical votes.

(2) There shall be no reporting or discussion with respect to any particular matter where the Expert Panel specifically so directs, e.g., where deliberations are incomplete or involve a sensitive decision which should not be released prematurely.

(3) There shall be no reporting or disclosure with respect to data or information prohibited from public disclosure pursuant to Section 51(b) of these procedures.

(4) Any notes or minutes kept or report prepared by any Expert Panel member or liaison representative shall have no status or effect whatever unless adopted as or incorporated into the official minutes or report by the Expert Panel. It shall be the responsibility of each Expert Panel member and liaison representative to make certain that the official minutes and reports are complete and accurate and fully reflect what happened at any meeting he attended.

Section 32. Additional Rules for the Expert Panel. (a) In addition to the rules established in these procedures, the Expert Panel may, with the concurrence of the Steering Committee, adopt additional rules which are not inconsistent with these procedures.

(b) Such additional rules shall be included in the minutes of the meeting when adopted and in the materials compiled pursuant to Section 27 of these procedures and shall be available for public disclosure pursuant to Section 51(a) of these procedures.

Section 33. Consultation by the Expert Panel with Other Persons. (a) The Expert Panel may consult with any person who may have data, information, or views relevant to any matter pending before the Expert Panel and, with the approval of the Director and the Chairman of the Steering Committee, may compensate such person and reimburse his expenses.

(b) Any interested person may submit to the Expert Panel a written request that it consult with specific persons who may have data, information, or views relevant to any matter pending before the Expert Panel. Such requests shall state why the specified person should be consulted and, if payment is requested, why the views of that person cannot reasonably be furnished to the Expert Panel by any other means. The Expert Panel, may, in its discretion deny
or grant such a request and, if payment is requested, with the approval of the Director and the Chairman of the Steering Committee, may compensate such person and reimburse his expenses.

**Section 34. Portions of Expert Panel Meetings.** An Expert Panel meeting shall have the following separable portions:

(a) The open public hearing. Every Expert Panel meeting shall include an open portion which shall constitute a public hearing during which any interested person may present data, information, or views, orally or in writing, relevant to the Expert Panel's agenda or other work. Such hearing shall be conducted in accordance with Section 39 of these procedures.

(b) The open panel discussion. The Expert Panel shall discuss any matter pending before it in an open portion of its meeting unless the meeting has been closed with respect to that matter pursuant to Section 36 of these procedures. No public participation is permissible during the open panel discussion portion of the meeting except with the consent of the Chairman of the Expert Panel.

(c) The closed presentation of data. Data and information which are prohibited from public disclosure pursuant to the provisions of Section 51(b) of these procedures shall be presented to the members of the Expert Panel in a closed portion of its meeting.

(d) The closed panel deliberations. Deliberations with respect to matters pending before the Expert Panel may be made in a closed portion of its meeting upon an appropriate determination by the Chairman pursuant to Section 36 of these procedures.

**Section 35. Notice of Public Hearing and Meeting of the Expert Panel.** (a) At least fifteen days before any meeting of the Expert Panel, the Administrator shall give public notice of such meeting.

(b) Such notice shall include:

1. The date, time, and place of the hearing and meeting.
2. A list of all agenda items.
3. If any portion of the meeting is closed, a statement of the time of the open and closed portions.
4. The time specifically set aside for oral statements by interested persons and for other public participation.
5. The name, address, and telephone number of the persons specifically responsible for the administrative support for that hearing and meeting.
6. A statement that written submissions may be made to the Expert Panel at any time pursuant to Section 38 of these procedures.

**Section 36. Determination to Close Portions of Expert Panel Meetings.** (a) No Expert Panel meeting shall be entirely closed unless no one requests an opportunity to make a presentation at the open portion for public participation. A portion of an Expert Panel meeting may be closed only pursuant to a determination by the Chairman, reflected in the minutes of the meeting, in accordance with this section.

(b) The following rules shall govern the closing of a portion of an Expert Panel meeting:
(1) Any determination to close a portion of a meeting shall restrict such closing to the shortest time possible consistent with the policy established in this section.

(2) Portions of meetings during which matters are considered that are prohibited from public disclosure pursuant to Section 51(b) of these procedures shall be closed.

(3) Portions of meetings during which the Expert Panel deliberates on the safety of cosmetic ingredients may be closed upon the determination of the Chairman that it is essential to close such portion of such meeting to protect the free exchange of internal views and to avoid undue interference with Expert Panel operations.

(c) A matter which is properly considered in an open portion of an Expert Panel meeting may instead be considered in a closed portion only if it is so inextricably intertwined with matters to be discussed in a closed portion that it is not feasible to separate them or discussion of the matter in an open portion would compromise or impinge upon the matters to be discussed in the closed portion.

(d) A closed portion of an Expert Panel meeting shall be attended only by Expert Panel members, liaison representatives, and the Cosmetic Ingredient Review employees, except as provided in Section 34(c) of these procedures for presentation of data and information which are prohibited from public disclosure pursuant to Section 51(b) of these procedures. Any person making a presentation described in Section 34(c) may be accompanied by a reasonable number of employees, consultants, or other persons with whom he has a commercial arrangement. If any person other than an Expert Panel member, a liaison representative, a Cosmetic Ingredient Review employee, or a person making a presentation described in Section 34(c) attends a portion of an Expert Panel meeting, that portion shall be open to attendance by any interested person.

Section 37. Administrative Remedies. Any person who alleges non-compliance by the Expert Panel or the Cosmetic Ingredient Review staff with any provision of these procedures may request appropriate relief from the Steering Committee.

Section 38. Written submissions to the Expert Panel. (a) Twelve copies of all written submissions for the Expert Panel shall be sent to the Administrator, unless an applicable public notice specifies otherwise.

(b) At the request of the Expert Panel, the Administrator may at any time issue a public notice requesting the submission to the Expert Panel of written data, information, and views pertaining to any matter being reviewed by the Expert Panel. Such notice shall specify the format in which the submission shall be made, the number of copies to be submitted, and the time within which submission shall be made.

(c) Any interested person may submit to the Expert Panel, through the Administrator, written data, information, or views on any matter being reviewed by the Expert Panel. Voluminous data shall be accompanied by a summary.
(1) Any such submission shall be distributed to each Expert Panel member and liaison representative, either by mail or at the next Expert Panel meeting, and shall be considered by the Expert Panel in its review of the matter.

(2) The Expert Panel may establish, and shall give public notice of, a cut-off date after which submissions relating to any matter shall no longer be received or considered.

(d) The Scientific Coordinator, through the Administrator, shall provide for the Expert Panel and liaison representatives all scientific data and information he concludes to be relevant to any matter being reviewed by the Expert Panel. Any member of the Expert Panel or liaison representative shall, upon request, also be provided any additional material available to the Cosmetic Ingredient Review which he believes appropriate for an independent judgment on the matter, e.g., raw data underlying any summary or report.

Section 39. Conduct of a Public Hearing Before the Expert Panel. (a) For each Expert Panel meeting, the open portion for public participation which constitutes a public hearing pursuant to section 34(a) of these procedures shall be at least one hour long unless the public participation does not last that long, and may last for whatever time the Expert Panel Chairman determines will facilitate the work of the Expert Panel. The public notice issued pursuant to Section 35 of these procedures shall designate the time specifically reserved for such public hearing, which shall ordinarily be the first portion of the meeting. Further public participation in any open portion of the meeting pursuant to Section 34(b) of these procedures shall be solely at the discretion of the Expert Panel Chairman.

(b) Any interested person who wishes to be assured of the right to make an oral presentation at a particular Expert Panel hearing shall so inform the Administrator or other designated Cosmetic Ingredient Review employee, orally or in writing, prior to the Expert Panel meeting.

(1) Such person shall state the general nature of the presentation and the approximate time requested. Whenever possible, all written data and information to be discussed by that person at the Expert Panel hearing shall be furnished in advance to the Administrator or other designated Cosmetic Ingredient Review employee. Such written material shall be mailed to the Expert Panel members and liaison representatives in advance of the meeting if time permits, and otherwise will be distributed to the Expert Panel members and liaison representatives when they arrive at the meeting. Such mailing or distribution shall be undertaken only by the Cosmetic Ingredient Review staff unless the Administrator specifically permits the person making the presentation to mail or distribute such material.

(2) Prior to the Expert Panel hearing, the Administrator or other designated Cosmetic Ingredient Review employee shall determine the amount of time allocated to each person for his oral presentation and the time that oral presentation is scheduled to begin. Each person shall be so informed in writing or, if the time prior to the hearing is short, by telephone. Joint presentations may be required by persons with common interests.
(c) The Chairman of the Expert Panel shall preside at the hearing and shall be accompanied by other Expert Panel members and liaison representatives who shall serve as a panel in conducting the hearing.

(d) Each person may use his allotted time in whatever way he wishes, consistent with a reasonable and orderly hearing. A person may be accompanied by any number of additional persons, and may present any written data, information, or views for the consideration of the Expert Panel.

(e) If a person is not present at the time specified for his presentation, the persons following will appear in order. An attempt will be made to hear any such person at the conclusion of the hearing. Any interested persons attending the hearing who did not request an opportunity to make an oral presentation shall be given an opportunity to make an oral presentation at the conclusion of the hearing, at the discretion of the Chairman, to the extent that time permits.

(f) The Chairman, other members of the Expert Panel, and liaison representatives may question any person during or at the conclusion of his presentation. No other person attending the hearing may question a person making a presentation. The Chairman may allot additional time to any person when he concludes that it is justifiable, but may not reduce the time allotted for any person without his consent.

(g) Public participants may question an Expert Panel member or a liaison representative only with that person’s permission and only about matters before the Expert Panel.

(h) The hearing shall be informal in nature, and the rules of evidence shall not apply. No motions or objections relating to the admissibility of data, information, and views shall be made or considered, but other participants may comment upon or rebut all such data, information, and views. No participant may interrupt the presentation of another participant at any hearing for any reason.

Section 40. Minutes and Reports of Expert Panel Meetings. (a) The Executive Secretary or other designated Cosmetic Ingredient Review employee shall prepare detailed minutes of all Expert Panel meetings, except that less detailed minutes may be prepared for open portions of meetings which are transcribed or recorded. The accuracy of all minutes shall be approved by the Expert Panel and certified by the Expert Panel Chairman. Such approval and certification may be accomplished by mail and by telephone.

(b) The minutes shall include:

(1) The time and place of the meeting.

(2) The names of the Expert Panel members, the Cosmetic Ingredient Review staff, and the liaison representatives as well as the names and affiliations or interests of public participants attending the meeting.

(3) A copy of or reference to all written information made available for consideration by the Expert Panel at the meeting.

(4) A complete and accurate description of matters discussed and conclusions reached. Such description shall be kept separately for the following portions of the meeting to facilitate their public disclosure: the open portion specified in Section 34(a) and (b), any closed portion during which a presentation is made pursuant to Section 34(c), and any closed deliberative portion
pursuant to Section 34(d). The minutes of a closed deliberative portion of a meeting shall not refer to Expert Panel members by name, except upon their request, or to data or information prohibited from public disclosure under Section 51(b) of these procedures. Any such inadvertent references which do occur shall be deleted prior to public disclosure.

(5) A copy of or reference to all reports received, issued, or approved by the Expert Panel.

(6) The extent to which the meeting is open and closed to the public.

(7) The extent to public participation, including a list of members of the public who presented oral or written statements.

Section 41. Transcripts of Expert Panel Meetings. (a) A transcript or recording is not required for any portion of an Expert Panel meeting.

(b) The Expert Panel shall decide whether any portion or all of its meetings shall be transcribed or recorded and, if so, by what means. Any such transcription or recording shall be arranged by the Administrator.

(c) If a transcript or recording of an open portion of an Expert Panel meeting is made by the Cosmetic Ingredient Review staff, or is made by an interested person and is submitted to the Cosmetic Ingredient Review, it shall be included in the record of the Expert Panel proceedings.

(d) If a transcript or recording of any closed portion of an Expert Panel meeting is made, it shall not be included in the records of the Expert Panel proceedings that are available for public disclosure. Any such transcript or recording shall be retained as confidential. The Chairman of the Expert Panel may, in his discretion, permit discussion without transcription or recording during any closed portion of an Expert Panel meeting that is otherwise being transcribed or recorded.

(e) Any person attending any open portion of an Expert Panel meeting may, consistent with the orderly conduct of the meeting, record or otherwise take his own transcript of the meeting. No person attending any closed portion of any Expert Panel meeting may record or otherwise take his own transcript of the meeting, except for an official transcript or recording arranged by the Administrator.

Section 42. Expert Panel Determinations. On the basis of all data and information submitted to it, the Expert Panel shall determine whether each ingredient, under each relevant condition of use, is safe, or not safe, or there is a lack of information needed to make a determination and insufficient industry interest in the ingredient at that time to justify obtaining the needed information. Upon making such a determination, the Expert Panel shall issue a tentative report pursuant to Section 44 of these procedures and a final report pursuant to Section 45 of these procedures.

Section 43. Working Teams of Expert Panel Members. Working teams of Expert Panel members may be designated to review information, to prepare draft documents, or to undertake other specific assignments for the Expert Panel, subject to the following conditions:

(a) The Chairman of the Expert Panel may appoint working teams comprised of from two to four members of the Expert Panel (one of whom may be
the Chairman of the Expert Panel) to review information about designated ingredients, to prepare draft documents for consideration by the entire Panel, or to perform other specific assignments for the Expert Panel. The Chairman of the Expert Panel shall assign a leader for each working team.

(b) A meeting of a working team is not a meeting of the Expert Panel and shall be governed by the procedures established by this Section and not by the procedures applicable to meetings of the Expert Panel.

(c) A working team shall meet at the call of its leader, issued through the Administrator. A working team may meet in Washington, D.C., or at another location if that location is more convenient for the working team members and conserves the resources of the Cosmetic Ingredient Review. Liaison representatives shall be advised of all working team meetings and may attend and participate. Only Expert Panel members, liaison representatives, and CIR staff may attend working team meetings, except upon the specific approval of the Chairman of the Expert Panel, the Director, and the Chairman of the Steering Committee.

(d) Any document distributed by a working team member to other members of the team, including a call for meeting issued by the team leader, shall be distributed through the Administrator, who shall also simultaneously send the document to the liaison representatives. The Administrator shall maintain a log and copies of all such documents.

(e) A working team may be assisted by the CIR staff, through the Administrator.

(f) A document prepared by a working team may be submitted to the Expert Panel by the leader of the working team, through the Administrator. The Administrator shall promptly distribute the document to Expert Panel members and to liaison representatives. Such a document should be received by Panel members and liaison representatives at least two weeks before the Panel meeting at which it is to be voted upon or otherwise considered.

(g) A working team document submitted to the Expert Panel is not a document of the Expert Panel unless and until the Expert Panel approves it. The Expert Panel may approve a working team document with or without revisions, may return the document to the working team for additional work consistent with the directions of the Expert Panel and the procedures described above, or may disapprove the document.

(h) Liaison members may describe to their constituencies the substance of a working team document, but may not quote from the document or make it available for reading or reproduction unless and until it is submitted to the Expert Panel and thereby becomes available for public disclosure. When a working team submits a document to the Expert Panel, the document becomes subject to the provisions of these procedures governing public availability of documents submitted to the Expert Panel and thereby becomes available for public disclosure (see Section 51).

Section 44. Tentative Report of the Expert Panel. (a) Prior to issuing a final report as described in Section 45 of these procedures, the Expert Panel shall issue a tentative report.
(b) The tentative report of the Expert Panel shall meet all of the require-
ments established for a final report in Sections 45(a) and (b) of these proce-
dures.

(c) The public notice of the availability of the tentative report shall provide
90 days within which any interested person may submit comments on the
tentative report and a request for oral hearing before the Expert Panel on the
tentative report.

(d) An oral hearing shall be granted by the Expert Panel on a tentative
report of the Expert Panel for good cause shown. Any such oral hearing shall be
conducted pursuant to the provisions of section 39 of these procedures.

Section 45. Final report of the Expert Panel. (a) With respect to each
cosmetic ingredient (or, where appropriate, closely related group of cosmetic
ingredients), the Expert Panel shall issue a final report. The final report shall
state the determination of the Expert Panel in accordance with Section 42 of
these procedures with respect to each ingredient and any relevant conditions
of its use.

(b) The final report shall contain the complete conclusions and recom-
endations of the Expert Panel with respect to the ingredient involved, includ-
ing a full explanation of the reasons for those conclusions and recommenda-
tions and references to the scientific information on which the Expert Panel
relies.

(c) The final report shall refer and respond to each point made in any
submission or oral statement made with respect to the tentative report pursuant
to Section 44 of these procedures.

(d) The Scientific Coordinator shall arrange for the publication of each
final report in an appropriate scientific journal. The Administrator shall other-
wise arrange for public dissemination of the final report.

Section 46. Amendment of a Final Report. (a) Any interested person who
believes that a final report is incorrect may petition the Expert Panel to amend
the final report to correct such error. The Administrator shall give public notice
of any such petition and all proceedings of the Expert Panel with respect to any
such petition shall be conducted pursuant to these procedures.

(b) A petition to amend a final report pursuant to this section shall ordinar-
ily be based upon new data and information not previously reviewed by the
Expert Panel. Such a petition shall be used primarily after the further data and
information requested by the Expert Panel in the final report with respect to an
ingredient, under each relevant condition of use, has been obtained, so that the
Expert Panel can proceed with final determination with respect to that ingre-
dient or condition.

(c) A determination by the Expert Panel with respect to a petition for
amendment of the final report shall be handled in the same way as the initial
determination by the Expert Panel. The Expert Panel shall first issue a tentative
report in accordance with Section 44 and then a final report in accordance with
Section 45.
Part E—Public Notice and Availability of Records

Section 50. Public Notice. (a) The Administrator shall give public notice of the availability of all Scientific Literature Reviews, the meetings of the Expert Panel, decisions and reports of the Expert Panel, and all other similar information, in both of the following two ways:

1. Such notice shall be mailed to a permanent mailing list consisting of representative members of the press (including interested newspapers, trade press, consumer publications, professional publications, and others) and representative interested organizations (including consumer, professional, and business organizations).

2. Such notice shall also be given by mailing it to specific individuals who have demonstrated a continuing interest through direct participation in the Cosmetic Ingredient Review except for individuals who are members of organizations to which notice is provided.

(b) Any interested individual or organization may request that it be placed on the mailing list for all public notices by written application to the Administrator. Any such request shall be accompanied by a statement of the need of such individuals for such notices. The Steering Committee may, in its discretion, impose a fee for providing such notices to all individuals, which shall be no greater than the actual expenses involved in providing them.

Section 51. Availability of Records for Public Disclosure. (a) The following records relating to the Cosmetic Ingredient Review shall be available for public disclosure at the following time, except as otherwise provided in paragraph (b) of this section:

1. The minutes of each Steering Committee meeting, after they have been approved by the Steering Committee and certified by the Steering Committee Chairman.

2. Each Scientific Literature Review, at the time it is completed and available in printed form.

3. Each chemical description, at the time it is submitted to the Administrator.

4. Each submission of safety information pursuant to Section 30(e) of these procedures, at the time it is received by the Administrator.

5. The written information made available for consideration by the Expert Panel at any meeting, at the same time that it is made available.

6. Any transcript or recording of any open portion of an Expert Panel meeting, as soon as it is available.

7. The minutes of any open portion of an Expert Panel meeting, after they have been approved by the Expert Panel and certified by the Expert Panel Chairman.

8. All written data, information, or views submitted to the Expert Panel at any open portion of a meeting, as soon as they are so submitted.

9. The minutes or portions thereof of any closed Executive portion of a meeting:

(i) For any matter not directed to be maintained as confidential pursuant to Section 31(h) (2) of these procedures, after they have been approved by the Expert Panel and certified by the Expert Panel Chairman.
(ii) For any matter directed to be maintained as confidential pursuant to section 31(h)(2) of these procedures, after the matter relevant to those minutes or portions thereof as acted upon by the Expert Panel or upon a determination by the Expert Panel that such minutes or portions thereof may be made available for public disclosure without undue interference with the operations of the Expert Panel.

(10) Any formal advice or report of the Expert Panel, after it has been issued by the Expert Panel.

(11) Any other Expert Panel records relating to the matter involved, except transcripts and recordings of closed portions of Expert Panel meetings, after the matter relevant to those records is acted upon by the Expert Panel, or upon a determination by the Expert Panel that such records may be made available for public disclosure without undue interference with the operations of the Expert Panel.

(b) The following records relating to the Cosmetic Ingredient Review shall not be available for public disclosure:

(1) Records relating to any cosmetic ingredient which has been determined by the Food and Drug Administration to be exempt from public disclosure pursuant to 21 C.F.R. 701.3(a) and 720.8(a).

(2) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall be available for public disclosure only in accordance with the regulations established by the Food and Drug Administration for public disclosure of such data and information in 21 C.F.R. 4.111(c)(3).

(3) All data and information relative to the nomination and selection of the members of the Expert Panel and liaison representative, in accordance with Section 21(e) of these procedures.

(4) A transcript or recording of any closed portion of an Expert Panel meeting, in accordance with Section 41(d) of these procedures.

(5) Documents of working teams of Expert Panel members which have not been submitted to the Expert Panel.

Section 52. Public Documents Room. (a) The Administrator shall establish a Public Documents Room, where one copy of all records available for public disclosure relating to the Cosmetic Ingredient Review shall be stored and available for public review. The Public Documents Room shall have adequate space for interested persons to examine such documents.

(b) Any person who uses the Public Documents Room shall sign a log showing his name, affiliation, time of entry and exit, and a general description of the documents reviewed.

Section 53. Public Inquiries and Requests for the Cosmetic Ingredient Review Records. (a) Public inquiries on all matters relating to the Cosmetic Ingredient Review shall be directed to: Administrator, Cosmetic Ingredient Review, 1133 Fifteenth Street, N.W., Washington, DC 20005, Telephone (202) 331-0651.

(b) All requests for records relating to the Cosmetic Ingredient Review, including records of the Expert Panel, shall be made to the Administrator.
(c) Copies of records that are publicly available pursuant to these procedures shall be made, upon request, for a fee that will reflect the actual cost of the labor and materials involved. The Administrator, with the approval of the Steering Committee, shall maintain a current price schedule for such copying.