THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION, INC.

NITROSAMINE AND NITROSATING AGENT REVIEW

FINAL PROCEDURES

AUGUST 24, 1978

Section 1. Definitions

(a) "Certified Public Accountant" means the firm of certified public accountants which has contracted with CTFA to perform services in connection with the Nitrosamine and Nitrosating Agent Review according to the terms of the contract and these procedures.

(b) "Contract Laboratory" means an analytical laboratory which has contracted with CTFA to conduct nitrosamine or nitrosating agent analyses according to the terms of the contract and these procedures.

(c) "Contract Monitoring Sub Task Force" means the Sub Task Force of the Nitrosamine Task Force which is responsible, in accordance with these procedures, for monitoring the activities of the Contract Laboratories to ensure that analyses are conducted in accordance with CTFA's contract with the Contract Laboratory and good laboratory procedures.

(d) "Coordinator" means the Coordinator of the Nitrosamine and Nitrosating Agent Review, who shall perform such tasks as are assigned to him by these procedures and by direction of the Nitrosamine Task Force.

(e) "Cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced onto, 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.

(f) "Cosmetic ingredient" means (1) any chemical substance, (2) combination of substances, or (3) packaging components, in the state

in which the substance is received from its supplier, used in the manufacture of a cosmetic product.

(g) "Cosmetic Ingredient Review" means the Cosmetic Ingredient Review program conducted by CTFA.

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

(i) "FDA" means the Food and Drug Administration, U.S. Department of Health, Education, and Welfare.

(j) "Ingredient Selection Sub Task Force" means the sub task force of the Nitrosamine Task Force which is responsible, in accordance with these procedures.

(i) For the selection of the cosmetic ingredients, combinations of ingredients, or other substances used in the manufacture or packaging of cosmetic products to be analyzed and the priority in which they are analyzed, and

(ii) The collection of cosmetic ingredients for analysis.

(k) "Nitrosamine and Nitrosating Agent Review" means the CTFA Nitrosamine and Nitrosating Agent Review conducted according to these procedures.

(l) "Nitrosamine Task Force" means the Task Force authorized by the CTFA Board of Directors to conduct the Nitrosamine and Nitrosating Agent Review.

(m) "Sample" means that quantity of a cosmetic ingredient which has been obtained for analysis pursuant to these procedures.

(n) "Sample Collector" means the person designated by the Ingredient Selection Sub Task Force to obtain samples of cosmetic ingredients for analysis by a Contract Laboratory.

Section 2. Purpose of the Nitrosamine and Nitrosating Agent Review

The purpose of the Nitrosamine and Nitrosating Agent Review is to conduct analytical tests on cosmetic ingredients used in the manufacture of cosmetic products to determine the presence and level, if any, of nitrosamines or nitrosating agents.

Section 3. Validation of Analytical Method

(a) In order to validate the nitrosamine and nitrosating agent analytical methodology, the Contract Laboratory or Contract Laboratory Monitoring Task Force will select and spike with a known quantity of nitrosamine or nitrosating agent a number of cosmetic ingredients.

(b) When the Contract Laboratory and Contract Laboratory Monitoring Sub Task Force are satisfied that the Contract Laboratory has developed analytical procedures that yield scientifically valid and replicable results, those analytical procedures will be submitted to the Nitrosamine Task Force for approval as having been validated.

(c) No samples will be analyzed by a Contract Laboratory until its analytical procedures have been approved as having been validated pursuant to (b).

Section 4. Selection of Cosmetic Ingredients for Review

(a) Analysis for Nitrosamines.

The Ingredient Selection Sub Task Force shall, with the approval of the Nitrosamine Task Force, select and rank in order of priority cosmetic ingredients for analysis of nitrosamine content by the Contract Laboratory in accordance with the following criteria:

(i) Examination of the chemical structure of cosmetic ingredients which, in the Sub Task Force's best scientific opinion, are capable of forming nitrosamines.

(ii) The frequency of use of cosmetic ingredients identified in (i) based on the Numerical Frequency List generated by FDA from all cosmetic chemical and trade names reported to FDA pursuant to 21 C.F.R. Part 720.

(iii) The ingredients in products analyzed by Dr. David Fine's laboratory and reported by him to contain nitrosamines. Reference: Fan, Y.Y., Goff, U., Song, L., Fine, D.J., Arsenault, G.P., and Bieman, K. N-Nitroso-diethanolamine in Cosmetics, Lotions and Shampoos, Food & Cosmetic Toxicology 15, 423 (1977).

(iv) Other ingredients reported to contain nitrosamines.

(v) Cosmetic ingredients not meeting the criteria in (i) through (iv), above, but which are used frequently, based on the FDA Numerical Frequency List, or in large volume in cosmetics and which are of high priority in the Cosmetic Ingredient Review.

(vi) The priorities established on the basis of the factors in (i) through (v) shall be subject to change on the basis of additional information as it becomes available.

(b) Analysis for Nitrosating Agents.

The Ingredient Selection Sub Task Force shall, with the approval of the Nitrosamine Task Force, select and rank in order of priority cosmetic ingredients for analysis of the presence of nitrite or other nitrosating agents by the contract laboratory in accordance with the following factors:

(i) The ingredients in products analyzed by Dr. David Fine's laboratory and reported by him to contain nitrosamines (see 4.a.(iii)).

(ii) Other ingredients reported to be nitrosating agents.

(iii) Frequency of use of raw materials, based on the FDA Numerical Frequency List, in the preparation of cosmetics.

(iv) The possible presence of nitrosating agents either by virtue of synthetic route, presence of corrosion inhibitors and/or presence of nitrogen oxides as a contaminant.

(v) Examination of the chemical structure of cosmetic ingredients which, in the Sub Task Force's best scientific opinion, are capable of being nitrosating agents.

(vi) The priorities established on the basis of the factors in (i) through (v) shall be subject to change on the basis of additional information as it becomes available.

Section 5. Determination of Number of Samples of Each Cosmetic Ingredient to be Analyzed

(a) The Ingredient Selection Sub Task Force shall, for each cosmetic ingredient selected for analysis in accordance with Section 4, determine the number of batches from which a sample is to be analyzed based upon the following criteria:

(1) The number of suppliers who offer the cosmetic ingredient for sale.

(2) The number of processes in which the cosmetic ingredient is used by cosmetic manufacturers, if known.

(3) The number of ways in which the cosmetic ingredient is made available to cosmetic manufacturers (e.g., in tank cars, vials, drums).

(b) When the Ingredient Selection Sub Task Force has determined the number of batches from which a sample is to be analyzed in accordance with the criteria in (a), it shall determine:

(1) The ingredient manufacturers whose products will be sampled.

(2) How many batches from each ingredient manufacturer will be sampled.

(3) How many samples from each batch will be collected.

Section 6. Sample Containers

The Ingredient Selection Sub Task Force will specify the type or types of container, including size and composition of cap and liner, to be used by a Sample Collector in obtaining a cosmetic ingredient for analysis. Samples submitted in nonconforming containers will not be analyzed.

Section 7. The Sample Container Label

The Sample Selection Sub Task Force shall develop a sample container label which meets the following criteria:

(a) The label shall be in three parts.

(1) Part One (Center Section) will contain space for the Sample Collector to provide the following information:

(a) Chemical name of the cosmetic ingredient sample.

(b) Trade name, if any, of the cosmetic ingredient sample.

(c) The manufacturer or other supplier of the cosmetic ingredient sample.

(d) The manufacturer or supplier lot number of cosmetic ingredient sample.

(e) The type of shipping container in which the cosmetic ingredient was received by the cosmetic manufacturer.

(f) The shipping history, to the extent known, of the cosmetic ingredient from the time it left the manufacturer or supplier to the time it reached the cosmetic manufacturer.

(g) The conditions under which the cosmetic ingredient was stored by the cosmetic manufacturer.

(h) The place where the sample was obtained (e.g., production line, storage lot, warehouse).

(i) The date the cosmetic ingredient sample was obtained.

(2) Part Two will contain space for the Sample Collector to provide the following information only:

(a) The chemical name of the cosmetic ingredient sample.

(b) The cosmetic ingredient sample is to be analyzed for nitrosamines presence.

(3) Part Three will contain space for the Sample Collector to provide the following information only:

(a) The chemical name of the cosmetic ingredient sample.

(b) The cosmetic ingredient sample is to be analyzed for nitrosating agent presence.

(b) The label shall be designed so that:

(1) Each part bears an identical and unique randomly selected number which shall not be visible to the naked eye unless an obvious and irreversible procedure is employed (e.g., removal of a protective covering).

(2) Parts One, Two, and Three are joined together in such a way that they may be separated at the appropriate time.

(3) The reverse side of Parts Two and Three bear an adhesive backing that will enable each to be securely attached to a sample container.

Section 8. Collection of Cosmetic Ingredient Samples for Analysis

(a) The Ingredient Selection Sub Task Force shall solicit samples of cosmetic ingredients selected for analysis from members of the Nitrosamine Task Force using a Sample Collection Request Form. The Nitrosamine Task Force member assigned the responsibility of obtaining a stated quantities of cosmetic ingredients will be known as the Sample Collector for that ingredient.

(b) The Sample Collector for a cosmetic ingredient shall not be an employee or agent of the manufacturer of that ingredient.

(c) The Sample Collector is responsible for:

(1) Obtaining the cosmetic ingredient from among the production supplies used in the ordinary course of cosmetic manufacturing.

(2) Assuring placement of the sample in the container specified by the Ingredient Selection Sub Task Force.

(3) Assuring that all information required on the sample container label is provided, and assuring that the label is affixed to the sample container or containers, as follows:

(i) If the cosmetic ingredient is to be tested only for nitrosamine presence, remove the protective covering from the back of Part Two of the label and affix Part Two, with Part One & Three still attached, to the sample container.

(ii) If the cosmetic ingredient is to be tested only for nitrosating agent presence, remove the protective covering from the back of Part Three of the label and affix Part Three, with Part One & Two still attached, to the sample container.

(iii) If a cosmetic ingredient from the same source (but constituting two separate samples) is to be tested for both nitrosamine and nitrosating agent presence, treat each as a separate sample.

(4) Arranging for delivery of the sample container to CTFA.

(d) The Sample Collector will keep no records concerning the sample he has collected.

Section 9. CTFA Procedure Upon Receipt of Sample

(a) When a sample container is received at CTFA, the Coordinator will inspect the sample container and label to determine:

(1) Whether the container is undamaged and contains its full contents.

(2) Whether all labels contain all required information, and are securely affixed to the appropriate sample container.

(3) Whether the protective covering over the randomly assigned code number is intact.

(b) If the Coordinator determines that a sample is not in compliance with Section 9(a)(1), he will destroy that sample and report the noncompliance to the Ingredient Selection Sub Task Force so that a substitute sample can be obtained. If the Coordinator determines that a sample is not in compliance with Section 9(a)(2), he will write to the collector to obtain required information and upon receipt he will forward to the Certified Public Accountant. If the Coordinator determines that a sample is not in compliance with Section 9(a)(3) he will retype the required information on a new undamaged label, affixing it to the sample

container in place of the damaged label. The damaged label will then be destroyed.

(c) When it has been determined that the sample container and its label are in compliance with these procedures, the Coordinator will:

(1) Record that the sample has been supplied and other appropriate information.

(2) Remove Part One (along with Part 2 or Part 3 as required) of the label and send it to the Certified Public Accountant.

(3) Arrange for delivery of the sample container with Part Two or Part Three of the label attached to the appropriate contract laboratory.

(d) The Coordinator will not remove the protective covering from any part of the label nor keep records in addition to that specified in Section 9(c)(1).

Section 10. Certified Public Accountant Procedure Upon Receipt of Part One of Label

(a) Upon receipt from CTFA of the label, the Certified Public Accountant will examine the label to ensure that the protective covering over the randomly selected sample code number is intact. If the protective covering is not intact, the Certified Public Accountant will:

(1) Notify the contract laboratory not to proceed with its analysis, or, if it has already done so, to destroy the results.

(2) Inform CTFA that the sample has been eliminated from the review so that the Coordinator may contact the Ingredient Selection Sub Task Force to obtain a substitute sample of the ingredient.

(b) If the protective covering over the sample code number is intact, the Certified Public Accountant will remove the covering and note the sample code number on any forms it deems necessary for the fulfillment of its role in this program.

(c) The Certified Public Accountant will devise manufacturer code numbers for each manufacturer whose products are analyzed pursuant to these procedures. The manufacturer code numbers shall be different for each cosmetic ingredient analyzed (e.g., ABC Company's D&C Violet No. 2 and Acid Orange 3 would be assigned different manufacturer code numbers).

Section 11. Contract Laboratory Procedure Upon Receipt of Sample

(a) Upon receipt of a sample, the Contract Laboratory will determine:

(1) Whether the container is undamaged.

(2) Whether the appropriate label is securely affixed to the sample container.

(3) Whether the protective covering over the randomly assigned code number is intact.

(b) If the Contract Laboratory determines that a sample is not in compliance with Section 11(a)(1)-(a)(3), it will not analyze that sample and report the noncompliance to the Certified Public Accountant, who will notify the Coordinator so that a substitute sample can be obtained.

(c) When it has been determined that the sample container and its label are in compliance with these procedures, the Contract Laboratory will:

(1) Remove the protective covering from the sample code number.

(2) Use the sample code number on all containers in which the cosmetic ingredient sample is subsequently placed, and on all documents which the Contract Laboratory generates in connection with that sample.

(3) Conduct the appropriate analytical procedures in accordance with its contract with CTFA.

Section 12. Contract Laboratory Procedure Upon Completion of Sample Analysis

(a) When a Contract Laboratory has completed its analysis of nitrosamine or nitrosating agent presence, as appropriate, it will notify the Certified Public Accountant of the analytical results providing the following information:

(i) Sample Code Number

(ii) Chemical Name of Sample

(iii) Analytical data

(b) The Contract Laboratory will release the information specified in (a), above, to no other person, and will keep and store its records in a secure facility.

Section 13. Role of the Contract Laboratory Monitoring Sub Task Force

(a) The Contract Laboratory Monitoring Sub Task Force shall direct and monitor the work of the Contract Laboratory to ensure that analyses are conducted in accordance with CTFA's contract with the laboratory and good laboratory procedures.

(b) To carry out its fuction, members of the Contract Laboratory Monitoring Sub Task Force may:

(1) Observe Contract Laboratory procedures.

(2) Communicate, orally or in writing, with Contract Laboratory personnel and officials concerning procedures, methods and data. All contacts are to be documented and forwarded to the Coordinator.

(3) Review and evaluate Contract Laboratory procedures, methods, and data.

Section 14. Certified Public Accountant Procedure Upon Receipt of Analytical Results from Contract Laboratory

(a) Upon receipt from a Contract Laboratory of analytical results in the form specified in Section 12, the Certified Public Accountant will:

(1) Record the results in an appropriate record.

(2) Within 48 hours of receipt, prepare the following information and forward it to the Coordinator:

(i) Sample code number

(ii) Manufacturer code number

(iii) Chemical name of sample

(iv) Contract Laboratory analytical results

(v) Shipping history of the sample as contained on Part One of the label

(b) The Certified Public Accountant will not provide CTFA with the trade name or the name of the manufacturer of the sample.

(c) The Certified Public Accountant will use the sample code number to determine the manufacturer or supplier of the cosmetic ingredient sample and, if it is a sample collected by CTFA, communicate, via first class mail, with the chief executive officer of the manufacturer as follows:

"Dear :

"The Cosmetic, Toiletry and Fragrance Association, Inc. is conducting an analytical program designed to survey cosmetic ingredients for nitrosamine and/or nitrosating agent content. This firm has been engaged by CTFA to ensure the confidentiality of the program. A copy of the CTFA procedures governing this program is enclosed.

"A sample of one of your company's products, [name of material and lot number], was selected for analysis as part of the CTFA program. (If more than one sample was collected, or if samples of more than one product were collected, you will receive a separate letter for each sample.)

We have now received the laboratory report on this product. These results are completely confidential. Neither the CTFA nor any other company will ever be able to correlate the laboratory results with the name of your company. The laboratory under contract to CTFA does not know the origins of the samples it analyzes."

"The only information which we are providing to the CTFA for each sample is the sample code number, the chemical name of the ingredient, the shipping history of the particular ingredient involved, a code number representing the results of the laboratory analysis, along with a unique code number which permits tracing the history of the sample.

"We have been instructed by CTFA to inform you that, under the procedures of the review, you will receive a copy of the laboratory results for your product. To keep this information confidential, kindly provide us in writing within 14 days of the date of this letter the name and address of the person within your organization you designate to receive the laboratory results. If you have not responded within 14 days, we will send the laboratory results to you at the address on this letter.

"The laboratory results relating to your product constitute neither an endorsement nor a condemnation of your product by CTFA. <u>These results do not show, of course, whether other batches of your product would yield similar results. These results apply only to the specific sample tested, and must not be taken to represent a usual, customary, or average value</u>.

"Should you wish to have a sample of your product, supplied by you and at your expense, analyzed as part of this program, please contact CTFA for instructions for your participation.

"We are authorized only to respond to written requests for information and not to engage in oral discussion about any aspect of this program.

"Sincerely,

"[Certified Public Accountant]"

(d) Fourteen days after the letter contained in (b) has been mailed, or sooner if the letter has been answered, the Certified Public Accountant will send to the person designated by the manufacturer, or, if none, to the chief executive officer, the laboratory results for that manufacturer's product. The results will be accompanied by a copy of the letter sent pursuant to (b) and the following cover letter:

"Dear :

"Two weeks ago, we informed your company that one of its products had been selected for analysis as part of The Cosmetic, Toiletry and Fragrance Association, Inc. Nitrosamine and Nitrosating Agent Review. A copy of our initial letter is attached. The analytical results for your product are as follows:

(1) [Product trade name]

(2) [Product chemical name]

(3) [Lot number of the product]

(4) [Analytical data].

"As we stated in our original letter, the laboratory results relating to your product constitute neither an endorsement nor a condemnation of your product by CTFA. These results do not show, of course, whether other batches of your product would yield similar results. These results apply only to the specific sample tested, and must not be taken to represent a usual, customary, or average value. If you have in your possession any information or data which reflect on the reliability or accuracy of the laboratory results and you would like to submit such information or data to CTFA for consideration by the Nitrosamine Task Force, you should send the information to: Coordinator, Nitrosamine and Nitrosating Agent Review, CTFA, 1133 15th Street, N.W., Washington, D.C. 20005 Please be advised that CTFA cannot guarantee the confidentiality of your submission if you choose to make one since it must by necessity be considered by the Nitrosamine Task Force. Also, you must agree in writing to waive the confidentiality of the analytical results pertaining to your product or products if this information is necessary to the understanding of your submission.

"Sincerely,

"[Certified Public Accountant]"

Section 15. CTFA Coordinator Procedure Upon Receipt of Analytical Results from Certified Public Accountant

(a) Upon receipt from the Certified Public Accountant of the information specified in Section 14(a)(2), the Coordinator will transmit to the Nitrosamine Task Force the information specified in Section 14(a)(2)(i), (iii) and (iv).

(b) The Coordinator will retain the information specified in Section 14(a)(2)(ii) and (v) until such time as he has received, for each cosmetic ingredient analyzed, sufficient information to determine whether release of the information specified in Section 14(a)(2)(ii) or (v) would permit identification of the ingredient manufacturer.

(1) If the Coordinator determines that release of the information specified in Section 14(a)(2)(ii) or (v) would not permit identification of the ingredient manufacturer, he will transmit the information to the Nitrosamine Task Force.

(2) If the Coordinator determines that release of the information specified in Section 14(a)(2)(ii) or (v) would permit identification of an ingredient manufacturer, he shall segregate that information and not release it to the Nitrosamine Task Force.

(c) This Section shall not be construed to limit the use of the information specified in Section 14(a)(2)(ii) or (v) under such conditions as the Coordinator believes would protect the identity of an ingredient manufacturer.

Section 16. CTFA Procedure Upon Receipt of a Request to Participate from an Ingredient Manufacturer

(a) A cosmetic ingredient manufacturer who expresses in writing in accordance with Section 14 (c) an interest in having an additional sample of its cosmetic ingredient analyzed as part of this Review may do so in accordance with the following provisions.

(b) The Coordinator will respond to the request for instructions as follows:

"Dear :

"This letter outlines the procedures applicable to analysis of manufacturer-obtained samples as part of The Cosmetic, Toiletry, and Fragrance Association, Inc. Nitrosamine and Nitrosating Agent Review. You are responsible for the cost of your participation at the rate of $_____ per sample. This sum represents actual cost of analysis plus overhead.

"If you wish to participate, you must agree to permit a member of the Ingredient Selection Sub Task Force serving as a Sample Collector to obtain a sample of the ingredient to be tested from your supplies. The Sample Collector will have the final decision as to which lot, batch or production run is to be sampled. Once a sample has been obtained from you, it will be treated in the same confidential manner as samples obtained from Sample Collectors.

"Please review the procedures which were sent to you by [Certified Public Accountant] . If you wish to participate, please forward to me:

"(a) A check sufficient to cover the cost of your participation.

"(b) A signed copy of this letter. Your signature will evidence:

"(i) Your receipt of a copy of the Review procedures.

"(ii) Your agreement to abide by the procedures.

"(iii) Your agreement to permit a Sample Collector to obtain a sample of his or her choosing of your product.

"(iv) Your agreement not to divulge the analytical results for your product to any person outside your company.

"Very Truly Yours,

CTFA"

Section 17. CTFA Procedure Upon Receipt of Sample Collected from an Ingredient Manufacturer

(a) Upon receipt of a sample container collected from an ingredient manufacturer, the Coordinator will follow the procedures in Section 9.

(b) In all respects, an ingredient sample obtained from a manufacturer is to be treated the same as a sample collected by the Ingredient Selection Sub Task Force.

Section 18. Collection, Analysis and Distribution of Data

(a) The Nitrosamine Task Force shall collect and analyze the data provided to it by the Certified Public Accountant.

(b) An ingredient manufacturer may submit to the Nitrosamine Task Force any information or data in its possession which reflect on the reliability or accuracy of the laboratory results. There is no guarantee of confidentiality on such submissions. Also the ingredient manufacturer must agree in writing to waive the confidentiality of the analytical results pertaining to his product or products if this information is necessary to the understanding of the submission.

(c) The Nitrosamine Task Force shall cause to be prepared, on a quarterly basis, or for such shorter period as the Task Force may determine, reports containing the analytical results received from Contract Laboratories during the preceding three months, or designated shorter period, except that incomplete data on a particular cosmetic ingredient or class of cosmetic ingredients which might be misleading unless the data were complete may be carried over to the next quarter or longer if required.

(d) The Nitrosamine Task Force shall provide to the Certified Public Accountant with sufficient copies of the reports prepared under Section 18(b) so that the Certified Public Accountant may provide a copy to each ingredient manufacturer whose product has been analyzed pursuant to these procedures.

(e) The Nitrosamine Task Force may prepare and distribute to CTFA members and other interested persons such additional data, analyses and information it develops from information available to it under these procedures.

Section 19. Nitrosamine Task Force Procedure Upon Request for Advice from Ingredient Manufacturer

Based upon the experience it has developed in conducting this Review, the Nitrosamine Task Force may advise ingredient manufacturers on methods and procedures designed to reduce nitrosamine and/or nitrosating agent presence in cosmetic ingredients only in accordance with the following procedures:

(1) The ingredient manufacturer requests in writing advice from the Nitrosamine Task Force.

(2) The ingredient manufacturer agrees in writing to waive the confidentiality of the analytical results pertaining to his product or products.

(3) The Nitrosamine Task Force will consult with, and render advice to, an ingredient manufacturer only during the course of a public meeting of the Nitrosamine Task Force.

Section 20. Ex Parte Communications

(a) There shall be no ex parte contact between CTFA, the Certified Public Accountant, and a Contract Laboratory.

(b) Ex parte communication shall mean any communication by whatever means between or among CTFA, the Certified Public Accountant, and a Contract Laboratory, except the following:

(1) Communications required or permitted pursuant to these procedures and in accordance with their terms.

(2) Requests for verification or duplication of communications required or permitted pursuant to these procedures and in accordance with their terms.

(c) Neither the Certified Public Accountant nor a Contract Laboratory may communicate with third persons concerning the program governed by these procedures other than in accordance with these procedures and in accordance with their terms. The Certified Public Accountant and a Contract Laboratory shall promptly report to the Nitrosamine Task Force any attempted or completed communication not permitted by these procedures.

Section 21. Information Available to the Public

(a) The Nitrosamine Task Force shall make available for public inspection at the offices of CTFA during regular business hours:

(1) A copy of these procedures

(2) The reports described in Section 18(c)

(3) Any documents distributed pursuant to Section 18(d).

(b) Any person who wishes to examine any of the documents described in Section 21(a) shall sign a log showing his name, affiliation, time of entry and exit, and a general description of the documents reviewed.

(c) Public inquiries on all matters relating to the Nitrosamine and Nitrosating Agent Review shall be director to: Coordinator, CTFA, Nitrosamine Task Force, Suite 1200, 1133-15th St , N.W., Washington, D.C. 20005. Telephone: (202) 331-1770.

(d) Copies of documents 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 Coordinator, with the approval of the Task Force shall maintain a current price schedule for such copying.

Section 22. Record and Sample Retention

The Certified Public Accountant and a Contract Laboratory shall maintain in a secure facility all documents and samples relating to the Nitrosamine and Nitrosating Agent Review for three years after completion of the Review. At the expiration of this period, the Certified Public Accountant and the Contract Laboratories will consult CTFA concerning the need for further retention of records and samples.

Section 23. 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 Nitrosamine Task Force shall be final and binding with respect to such matter.

(b) These procedures may be amended by a two-thirds vote of the Nitrosamine Task Force, with the approval of the CTFA Board of Directors.