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together with their requested classification. The German Dyestuff Commission already has our safety data for these colors and, I feel that in the interest of international cooperation, and if the toxicological data supports it, we can expect early listing of such colors as FD&C Green 3, D&C Red 17, D&C Red 31, D&C Red 33, D&C Red 6, D&C Blue 6, D&C Orange 17 and External D&C Violet 2. Furthermore, the Commission can be requested to broaden allowed uses of such colors as FD & C Blue 1.

The meeting closed with a call for continued International exchange of scientific information.

The success of this meeting was made possible by a large number of people, too many to name here. However, three men deserve special thanks.

Dr. Opdyke's contribution was enormous in magnitude. His many months of work in studying data and in developing strategy for the meeting, as well as his fantastic performance throughout the meeting doubtlessly had a great effect on its outcome.

Dr. Goswin Van Ham of Margaret Astor Cosmetics in Germany, and Dr. Otto Jacobi of Kolmar Laboratories, came to the U.S. for the express purpose of painstakenly examining our data and translating it into tables in German for consideration by the Commission.

The cosmetic industry owes these men and our friends in Germany a debt of gratitude for their efforts on its behalf.

CTFA-FDA — Scientific Liaison Report

Dr. Harold Schwartz*

Since the last Scientific Conference, three meetings of the CTFA-FDA Scientific Liaison Committee were held.

It has been most interesting and certainly gratifying in many ways; interesting because each meeting brought forth new questions, problems, and occasionally even resolutions of some of those problems; gratifying because I believe for the first time, sound scientific discussion represented the atmosphere at our meetings.

It is my recollection that approximately thirty different subjects were thoroughly discussed. From our ingredient survey to such widely diverse subjects as chloroform use in toiletries, bubble baths, color petitions, mercury in cosmetics, microbiology, etc., were discussed. When requi problems were studied in separate sessions. Very often subject matter became so deep and so important to ev one, that a special committee of scientists was required, we brought in people from outside in order to assist w necessary.

For example, when the question of asbestos in talc c up, people who were interested in talc and who were perts in the field of analysis of talc were brought in so the subject could be thoroughly handled on a scienti basis. Dr. George Wolcott mentioned how a group formed in order to study chloroform in toiletries, especi in dentrifices. Hexachlorophene and other subjects w discussed at these joint meetings held by scientists and by compliance people. I really have to emphasize this cause I think our biggest hang-up when we first started to determine that this committee would meet and dis only on a scientific basis and certainly not on a legal or compliance basis. I believe, certainly in the last year, t we have been conducting our business in that manner.

Much of the success of our committee is due to participants.

Through the leadership of Commissioner Edwards his staff, Dr. Wodicka, Dr. Schaffner, and all other FD participants, a willingness to deal with scientific probl on a scientific basis has been demonstrated.

Additionally, accolades must go out to all the mem of the CTFA participating in this joint venture. They h worked diligently, controlled their tempers for the m part, and I believe have performed a noteworthy service.

Certainly much of the uneasiness about discussing pr lems with FDA has noticeably decreased and, I say thi the face of what I believe are the most trying times.

Not only our industry, but FDA is feeling great pressu from such sources as consumer groups, Congress, and so o and yet, the discussions have been kept on a rather e keel.

The best way to describe the kinds of activities that group has participated in would be to just read the age of our last meeting which was held in Washington August 18th. It represents a far cry from the sparring t took place some two-and-a-half years ago at the first s sion.

This Agenda reads as follows: —

1. CTFA Petitions
2. Color Additives
3. Hair Coloring Research
4. Chronic Eye Studies
5. Hexachlorophene
6. Feminine Deodorant Sprays
7. Aerosols
8. Asbestos in Talc
9. Chloroform
10. Shampoos
11. Microbiology
12. Mercurials
13. Hypoallergenic Cosmetics
14. Organic or Natural Cosmetics

This agenda certainly covers a wide gamut that affects all us.

I hope that we continue to approach scientific problem affecting our industry with forthrightness, without vind

*The Mennen Company, Morristown, N.J. 07960

...reness, and with an openness dedicated to resolving problems of the present and avoiding problems of the future. I believe the FDA-CTFA Scientific Liaison Committee will continue to approach problem solving with those criteria in mind.

Discussion of Voluntary Petitions

James H. Merritt, Moderator
Dr. Murray Berdick
Dr. Harold Schwartz
John C. Warley, Jr.

James H. Merritt

The subject of our discussion this morning, our Petitions, really has its genesis a couple decades ago when there was first introduced in Congress legislation to require pre-clearance of cosmetics before they were marketed. That legislation has been introduced repeatedly. Congress, in its wisdom, has not enacted it. It has felt, and I think rightfully so, there are more pressing problems for the Food and Drug Administration.

With the knowledge that pre-clearance legislation had been introduced several times and with the knowledge too that in the color additives suit there were efforts made to interpret the regulations as including pre-clearance, this Association, then known as TGA, met and decided to develop and promulgate, if possible, a system of self-regulation on a voluntary basis.

We contend that self-regulation will be just as effective, will be much more economical than mandatory regulation, and, will provide the consumer an adequate level of protection so that the consumer will be protected against those injuries or that harm which might come from unsafe products.

The first two steps in the program of self-regulation were filed with the Food and Drug Administration several months ago. They involved two petitions, to be promulgated under the Food, Drug and Cosmetic Act as voluntary regulations. They have since been published in the Federal Register for comment.

Now, first on our office staff team, I am going to call on John Warley, a lawyer, who will discuss the concept involved in the two petitions filed; the first, or voluntary registration of manufacturers; the second, for the voluntary disclosure of ingredients.

John C. Warley, Jr.

I'm going to be discussing some of the legal and regulatory overtones to these petitions; and, I won't get very scientific for obvious reasons. Two items — where cosmetics are made and what is in them — have been a top priority on FDA's list for some while; and, they are now a top priority on the CTFA and the cosmetic industry's list, as well.

In considering the steps by which information could be submitted to FDA on the location of manufacturers and the ingredients in cosmetics, there were basically two paths open to the industry:

One was mandatory regulation.

The other was voluntary regulation.

The mandatory regulation seemed at first, I suppose, to be the most obvious way to go because voluntary regulation in this context had never really been attempted by an industry before.

Therefore, the petitions which we submitted, and the steps which we are taking in submitting this information to the government is, I think unprecedented in the field of statutory regulation. For that reason perhaps there are few precedents for us to follow and the regulatory road might be a bit rocky for a while, but we are sold on the concept.

For a number of reasons we chose the voluntary regulation route. First and foremost was our conviction that this industry would cooperate in supplying the information to the government; that it did not have to be coerced into submitting the information and that it would be something of a grand gesture on industry's part to comply fully and to show the government and the consumer that there is a conscientious soul in industry which is going to cooperate where cooperation is needed.

We submitted two petitions.

Most of you, I feel sure, have seen them by now. If you haven't had a chance to scrutinize them, you at least know of their existence. The first calls for the registration of manufacturers and packagers of cosmetic products.

You will be asked to file with the Food and Drug Administration a registration for all of your plants, factories, etc.

In return, you will receive from them a plant registration number which you will use with future correspondence with the agency.

The second petition is for the filing of cosmetic ingredients in classes. By classes I mean between fifty and a hundred per cent, twenty-five and fifty percent, etc. on down.

So, it is not a completely quantitative formulation but it is completely qualitative, with the exception of flavors and fragrances, whose composition, due to their complexity and the great number of ingredients involved, is not requested.

The information will be submitted in order of decreasing predominance and there is a very strict legally binding confidentiality provision by which the FDA will be precluded from revealing this information submitted on the product ingredients statement to anyone, except under very certain spelled out and defined conditions.

In our grounds for submission to the Food and Drug Administration we stated that in our belief the information we were providing was necessary for FDA to do its job under the Food, Drug, and Cosmetic Act and to carry out the responsibility that the public has charged that agency with, and since we have acknowledged the fact that the information is necessary for FDA to do its job, it puts us in a very paradoxical position not to give them the information that we have spoken of.

We are encouraging support for these. We think support will be forthcoming and if for some reason it is not, then it

Pharmacology & Toxicology

Robert Giovacchini, Ph.D.*

1972 COMMITTEE REPORT

I should like to begin by first discussing the Inter-Industry aerosol testing program, which was formed as a subcommittee under the pharmacology and toxicology committee. This program involves the safety evaluation of propellants and several contracts have been let in this area.

The first one is to Dr. Richard Stewart of the Medical College of Wisconsin. This is an evaluation of the absorption, excretion, and physiological effects, both under acute and subacute exposure in humans using a wide range of propellant concentrations and exposure times.

There is an associated study going along with this which is being funded completely by the du Pont Company, which is an evaluation of propellant levels under conditions of use. This study is being done to insure that the concentrations utilized in the Stewart study will be more than that seen under normal use conditions.

The second study has been funded and is in progress at the University of Maryland College of Pharmacy under Dr. David Blake. This study examines the biotransformation and metabolic fate of propellants, the study beginning first in rats moving onto dogs and later to humans.

The third study has been funded at the Medical College of Georgia with Dr. Nancy Flowers. It's a study which is examining the early changes in the electroconduction system of the heart following exposure to propellants; dogs are utilized in this study.

On Wednesday the Inter-Industry Aerosol Subcommittee will meet to discuss three additional areas where protocols have been made available. One deals with the effects of propellants on the mucocilliary system, a second area deals with the effects of propellants on pulmonary cytology, and the third deals with health status surveys of people exposed to propellants.

The Pharmacology and Toxicology Committee has had task forces working in basically 17 other areas, and I won't cover all 17. Quickly I'd just like to summarize a couple of them. One is a task force under Dr. Guido Battista (Warner-Lambert) which is dealing with ways and means of handling poison control information.

In addition we've been working with the committee that Dr. Berdick referred to which is looking for methodology for the safety evaluation of eye-are colors. We're looking into the area of antimicrobials as well as – a program for dermatologists, and additional guidelines for the safety evaluation of cosmetic products.

*Gillette Medical Evaluation Laboratories, Rockville, Md. 20850

One thing that has come up and I've been directly involved with is the OTC-FDA Antimicrobial Review. I need not say what this review panel has done up to now, I think everyone who reads the newspapers is aware of what's happening. We are scheduled to meet again this week to deal with the safety and efficacy of TBS, TCC, and DP 300.

1973 COMMITTEE REPORT

This year has been a busy and progressive year for the members of the Pharmacology and Toxicology Committee. I think there have been times when we felt like we were like the last group to leave Dunkirk or members of the Charge of the Light Brigade. In spite of all this, we've worked in several very definitive areas. I'd like to cover them in the order that I've got them on my list – which is not necessarily the order in which they were handled.

One of the major problems that we concentrated on this year was the Poison Control Center Program. This was a program that was developed with the – then the poison control center within the Food and Drug Administration. This unit at this moment is part of the Consumer Product Safety Agency. The thrust of the program was (1) how does one handle Poison Control calls for cosmetic type products, and (2) how can such a program be placed in the CPSC Poison Center computer in an all-encompassing procedure for the members of the industry. Dr. Guido Battista, headed this task force of Pharmacology and Toxicology and with his task force group put together a list of, if you will, generic type formulations, and the types of antidote procedures that might or might not be required. This document, at the present time, has gone to the Scientific Advisory Committee and will be moving its way up through CTFA before being sent out to the industry for comment and review. The second program that we're working on is entitled the Program for Dermatologists. If a physician-dermatologist were to contact you with respect to patch testing, or a consumer with respect to an alleged, allergic reaction, how should one handle it? This program will shortly be reviewed by the Pharmacology and Toxicology Committee and then will also begin working its way up through CTFA for review. It describes various ways in which the industry can handle these types of situations prudently and scientifically.

The third major program we have been working on for the year have been guidelines for Prognostic Safety Evaluation of Cosmetic and Toiletries Products. We are trying to develop the safety guidelines based on product categories. Thus, you will have a checklist, not a litany of tests. As you develop a product within a certain product category, you can use the checklist to see the areas of possible concern. The table can be used as a review. As you examine your product vs. the checklist do you believe there may or may not be a problem with respect to, for example, ophthalmic irritancy, dermal irritancy, etc. Then you can decide if additional studies are needed. Also, you may conclude that no studies are required. We want to be very clear on the fact that in going through this checklist, you might conclude that you have sufficient evidence in your files that you don't have to do a specific test. There may be sufficient evidence from the medical literature that lets you conclude that you don't have to do a test. It's the sort of review to go through to ascertain whether or not you have sufficient

information for the safety of that particular product before you go to market.

Other areas that the Pharmacology and Toxicology committee task forces have been involved in – include ophthalmic pigmentation; Dr. Costello and his group are working on a review of saccharin for use in oral products; a chloroform safety review; eye anesthesia and shampoos; asbestos and talc; support to the color additives committee; and, a review of the EEC lists with respect to ingredients.

An area that we're going to be moving into, with Dr. Lanman, in charge of this task force, and now that Dr. Estrin has the funds to hire staff, will be a review of the medical literature with respect to antimicrobial ingredients. We shall be requesting from companies any internal information they may have on the safety of antimicrobial ingredients.

Microbiology Committee

Charles Goldman, Ph.D.*

1972 COMMITTEE REPORT

The Microbiology Committee has been very active during this past year. All of you in this room have been caught up in the various pressing problems which beset our industry today. The fact that there are virtually no pressing, microbiological crises which are facing our industry is the best measure of our committee accomplishments.

The members of this committee, and the various subcommittees, deserve recognition for their contribution to the cosmetic and toiletry industry. This has only been possible because of the support and the committment of the various member companies of the CTFA. Our Preservation Subcommittee, which is under the chairmanship of Dr. John Smith of Chesebrough-Pond's, has completed a collaborative study involving microbial challenge of cosmetic formulations, with pure and mixed cultures and using both qualitative and quantitative methods for assessment. This paper will be published in the near future. This subcommittee also has compiled a list of microbial cultures in order to facilitate the exchange among various CTFA member companies.

James Rodgers (Mennen) who is a member of this subcommittee, is currently investigating a standardization procedure using dioxin as the reference. If this approach proves feasible, a larger collaborative study will be done. Currently member laboratories are starting another collaborative study to evaluate the rechallenge method demonstrating the efficacy of a preservative in a test cosmetic formulation.

*Avon Products, Inc., Suffern, N.Y. 10901

The Microbial Content Subcommittee under the chairmanship of Dr. S. Mark Henry (Bristol-Myers) has prepared a document entitled The Microbial Limit Guidelines for cosmetics and toiletries. This document was recently approved by the board for distribution to CTFA member companies. This subcommittee also has sent out forms for the completion of a CTFA study on the microbiological status of products produced by CTFA member companies. The study will encompass a total of 4,000 products. A preliminary pilot study covering 100 products has been conducted by cooperating laboratories.

The subcommittee is continuing to study methodology with regard to the classification and isolation of various types of microorganisms. Mr. John Yablonski (Avon) of this subcommittee is coordinating the work on a simplified methodology for classifying microorganisms. This is intended for use by quality control microbiologists.

This subcommittee is also functioning in the area of maintaining the file of microbiological cultures which can be used for preservation tests and other testing procedures. The list of cultures will be made available to those member companies who submit a list of cultures in their own culture collections.

Our Education and Information Subcommittee has completed a slide presentation which can be seen in the exhibit area. The professional quality of this presentation is the best tribute which can be given to the efforts of this committee. This slide presentation will be made available to member companies.

This subcommittee also played a most vital role in planning and coordinating a Raw Materials Seminar which was held in Saddlebrook, New Jersey last June. This was the first meeting of its kind covering this most important area in the microbiology of cosmetic products.

The Microbiological Aspects of Quality Assurance Subcommittee during the past year has completed a document entitled Quality Assurance Procedures for the Management of Process Water. The CTFA Board of Directors has recently approved this document for distribution to the CTFA membership.

The entire subcommittee participated in the discussion and participation on the management of demineralized water systems at the Raw Materials Seminar held at Saddlebrook last June. The subcommittee has also completed preliminary drafts of a document entitled Cleaning and Sanitizing Equipment. This was submitted to the Quality Assurance Committee whose chairman is Mr. William Fead. A draft of a document entitled a Check List for Inplant Inspections was prepared and submitted to the Microbiology Committee.

The Raw Materials Subcommittee consists of two branches, one is located on the West Coast and is under the direction of Dr. David Anderson of Max Factor. The other is located on the East Coast and is headed by James Rodgers of the Mennen Company.

During the past year, this subcommittee participated in the symposium on the microbial content of raw materials. Various raw material categories for round robin testing were selected and technical conferences were held with invited suppliers on the particular raw materials which were under study. This group is to be congratulated for the work that was done, and a very fine conference in which they participated.

and now NMR equipment is available in the same price range as infrared equipment.

The particular significance of NMR for identification is that the structure of an organic molecule could readily be deciphered from its NMR spectrum. This cannot be done easily by infrared and this is what makes NMR very attractice for identification purposes.

We are using NMR primarily for identification of those compounds which are quite indistinguishable by IR such as a homologous series, which differ only by a methylene or an oximethylene group.

The polyoxyethylene sorbitanes all give a very similar IR spectra, while the NMR spectra can readily distinguish these closely related compounds.

As simple identifications have become more and more instrumental, the assay procedures have also followed the same path. The introduction of ultraviolet spectrophotometry about 25 years ago completely altered analytical procedures and made possible many accurate analyses where before then only semi-quantitative determinations were possible.

The great change in our day was the expansion of the use of all forms of chromatography. Gas chromatography has been of particular importance to our industry. The instrumentation is relatively inexpensive, simple, and is capable of analytical separations unheard of previously. It is now possible for the first time to determine in detail the composition of many raw materials.

Fatty acid analysis has become a routine procedure and enables us to have a greater control over our products.

Gas chromatography has been applied to all types of raw materials and finished products, and its use is growing at a very rapid rate. We have been introducing GC methods into our standards and quite a number are to be found in the latest edition of the CTFA manuals.

A very recent development in chromatography has been the introduction of high speed liquid chromatography. The manual column procedure in use for many years has been revitalized, and with the application of high pressure pumps, the speed of separation has been greatly accelerated. Separations that previously took hours or days can now be accomplished in a matter of minutes. Heat sensitive bio-materials which cannot be handled by gas chromatography can readily be separated by high pressure liquid chromatography at room temperature. The growth of this technique parallels that of GC in the '60's, and there is no doubt that we will be publishing methods using this technique in future editions of the CTFA manuals.

In all areas of analysis the tendency has been to be increasingly concerned with the minor trace components of the materials. We have been testing for arsenic and lead for many years, using the classical laborious wet chemical procedures. As the need for testing trace metals became more apparent, the technique for accomplishing this was also developing. This last decade saw the introduction of atomic absorption spectrophotometry and made it possible to analyze for most trace metals in the parts per million range.

What was once a horrendous analytical problem can now be performed on a routine basis. This new method has already been incorporated in one of our standard methods of metal analysis, and in the future many more trace metals will be tested in this way.

With the application of computers to analytical chemistry, it is now possible to combine all the data obtained from the new instrumentation and to automate many of these procedures.

The next decade will show even more growth as the available technology is absorbed and becomes common practice. We no longer can resist the influx of this developing methodology. The only rational approach is to accept the inevitable changes that are almost upon us and take advantage of the new opportunities that are now available.

REDACTED

The CTFA Talc Subcommittee was established in September 1973. Its first assignment was to evaluate the optical microscope method for the detection and estimation of asbestos minerals in talc used for foods and drugs, which was published in the Federal Register of September 28, 1973, as an FDA proposal. The minerals were identified by the use of refractive index mounting liquids.

Talc

George W. Sandland
Bristol-Myers Company

Based on the application of the published method to the analysis of seven different talc samples, ten scientists presented data which indicated lack of reliability and reproducibility in the method. Four of the investigators disqualified themselves due to uncertainty and lack of confidence in their interpretations.

A report describing the round robin was filed with the Hearing Clerk in December 1973, along with a recommendation to delay finalizing the proposed regulation until further work could be

done either to modify the optical microscopic method or to develop more satisfactory methodology.

The subcommittee agreed to form an Ad Hoc Methodology Committee to be headed by Dr. Robert Rolle of Johnson & Johnson. Scientists from government and industry were invited to participate on this committee. Every known method was considered by the committee, including refinement of the optical microscopic method to include the use of dispersion staining. The microscopic method was finally abandoned as a general procedure due to the lack of confidence in the sample size, and the inability to resolve particles which are submicron in size. The microscopic method was found to have some value, however, when used with dispersion staining, for the confirmation of fibrous amphibole.

The work of the Ad Hoc Methodology Committee eventually led to the selection of differential thermal analysis (DTA) for the detection of chrysotile, but this method has the disadvantage of lack of specificity for chrysotile since it detects other serpentine minerals as well. The only known backup method for a positive identification in this event, is transmission electron microscopy with selected area diffraction. This equipment is very expensive and is not readily available. It was also agreed, though, that despite many efforts, the committee had been unable to find a sample of cosmetic talc containing naturally occurring chrysotile, and that indeed there may not be such an entity; therefore, a backup method would not be necessary anyway. If this be true then, it was asked, "Why should we test for chrysotile if there isn't any?"

This resulted in a survey of the industry wherein data were accumulated for a total of 3397 analyses of cosmetic talc. Incidentally, the manufacturers and suppliers of cosmetic talc have been monitoring for chrysotile since 1971 and some have done so since 1968. Not one single sample analyzed in this total, showed a positive detection of chrysotile. Based on these data, the Talc Subcommittee has recommended that it should not be necessary to monitor cosmetic talc for chrysotile.

The Ad Hoc Methodology Committee has developed a method for the detection of fibrous amphibole using continuous scanning X-ray diffraction plus optical microscopy with dispersion staining. The latter procedure is necessary in the case of a positive result by X-ray. The method has a detection limit of about 0.5 percent and offers the advantage of a more statistically valid sample size, at two grams compared with the optical microscopic method which examines a portion of a one milligram sample.

The Talc Subcommittee has recommended to the CTFA Standards Committee that a revised standard for cosmetic talc be issued, with updating to include specifications for Fibrous Amphibole at "none detected," Free Crystalline Quartz at "As specified by buyer," and X-ray as an alternate to IR for identification. Since some perfectly good cosmetic talcs contain dolomite or calcite, which are acid soluble, the limit for acid soluble has been increased to 6.0 percent.

The Standards Committee has accordingly updated the standard for cosmetic talc and the recommended methods will be included. At this moment the new standard has been edited and submitted for printing.

Future plans include further study of trace impurities in cosmetic talc and the standard will be further modified, when, and as found necessary.

Another very important phase of our work involves the motivation of the cosmetic talc suppliers to label their containers in such a manner so as to identify cosmetic talc as CTFA Grade and thereby signify that it has been adequately monitored to conform with the published CTFA Standard.

Considering that CTFA members buy 85 to 90 percent of the cosmetic talc used in this country, and that the major suppliers of cosmetic talc participated in the development of this standard, its issue should do much to provide adequate control, and ensure that a suitable grade is furnished to the market.

We are indebted to Bob Rolle of Johnson & Johnson and all the other dedicated scientists who participated in this work.

Producing quality products is a very obvious goal of all cosmetic manufacturers. Success in achieving this goal has helped to make the cosmetic industry one that is dynamic and fast growing. This rapid growth, coupled with increasing consumer pressure and legislative demands, has made the CTFA guideline program more valuable and more necessary. The work of creating these guidelines demands a meaningful technical dialogue among participating companies.

Quality Assurance
Alayne Zatulove
Estee Lauder, Inc.

There are 16 different firms represented on our Quality Assurance Committee, and during

The CTFA Standards Committee has the responsibility for establishing up-to-date chemical and physical specifications for ingredients used in cosmetic products. The standards, which consist of a six-volume set: Specifications, Methods, Spectra and three volumes of Cosmetic Ingredient Descriptions (CID's), are continuously being added to and updated. The Standards Committee relies upon its members to contribute laboratory time to the initial testing of raw materials and the statistical establishment of specifications for the parameters studied.

Standards
Monroe Messinger
Chesebrough-Pond's Inc.

This past year has been a particularly difficult one for our laboratory testing activity. However, in spite of external obstacles, there has been significant progress. As of May 1975 we had issued a total of 130 CTFA specifications, 123 CTFA spectra and 141 CTFA methods. Since March 1976 approximately 25 methods have been completed, as well as a corresponding number of spectra.

The Cosmetic Ingredient Description subcommittee of the Standards Committee, under the chairmanship of Dr. Fred Lowman, has prepared and approved for publication, 90 CID's, since the last printing and distribution of the CID list. Approximately 20 CID's are being prepared by several members of the subcommittee, and an additional 25 materials have been identified as cosmetic ingredients currently in use from the FDA list of ingredients of cosmetics and drugs.

The Talc subcommittee, with George Sandland as its chairman, has completed a revised standard which is designed to control the quality of cosmetic grade talc. It will help to assure that talc used by our membership will meet the high standards of our industry. Among the revisions and improvements in this standard are the inclusion of limits for fibrous asbestiform amphibole and quartz minerals, along with suitable methodology for quality assurance applications. An alternate method for identification has also been added in the use of an X-ray defraction procedure.

There is much work that remains, in the continuing activity of the Standards Committee, in reviewing the cosmetic ingredient descriptions and converting them into standards. The emergence of the Cosmetic Ingredient Review program will certainly increase the participation of the Standards Committee and/or its subcommittees.

We extend our appreciation to all members of the Standards Committee and to its subcommittees for their valued participation in the standards program.

The Microbiology Committee is composed of the main committee and five subcommittees: Education and Information, chaired by Frank Wertalik; Microbial Content, chaired by Warren Mulston; Quality Assurance, chaired by Jack Bachelor; Preservation, chaired by Emily Owen; and Raw Materials, chaired by Margaret Dolan. There are approximately 30 companies or their divisions represented, with 45 microbiologists participating in the various activities. I would like to update you to their accomplishments and future objectives.

Microbiology
James Rodgers
The Mennen Company

Education and Information. You have undoubtedly noticed our booth in the Exhibit Area. The first preview of the latest slide/tape presentation, entitled, "Cleaning and Sanitation of Manufacturing Equipment," is being shown. Also on display are our previously completed slide/tape presentations: "Microbes, Sanitary Practices and You," "Determination of the Microbial Content of Cosmetics and Toiletries," "Treatment and Handling of Process Water," and "Speciation of Yeasts, Molds and Staphylococci."

The Education and Information subcommittee is also preparing for the industry debut of "Wally and Wanda Whitehat." This is a new poster program series, designed to help stimulate greater awareness of good sanitary practices. In addition, the "Microbiology Forum," presented in each issue of the *CTFA Cosmetic Journal*, is spearheaded by this subcommittee.

Microbial Content. The joint papers, "Methodology for Microbial Content of Finished Products National Survey" and the "National Microbiological Survey of Cosmetics and Toiletries, 1972-1975," have been completed and made available for publication by the CTFA.

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1977 Annual Meeting Reports

CTFA's scientific department in 1976 again demonstrates its flexibility in meeting new challenges and responding to long-range needs of the industry.

Scientific Advisory Committee
Dr. Robert Giovacchinni
The Gillette Company

Time does not permit me to do more than list a few typical committee accomplishments for 1976:

TECHNICAL GUIDELINES: Two new ones —safety substantiation and manufacturing coding—were added to an already substantial number available to manufacturers to assist them in developing their own quality assurance programs.
VISUAL AIDS: The fifth in a series of audio-visuals—this one on "Cleaning and Sanitization of Plant Equipment" has been prepared to help you in your training programs, and is now in production.
DICTIONARY: New edition covering double the number of ingredients in the 1973 edition will be in the mails in March.
STANDARDS: A major supplement will be published in 1977.

Here's a sampling of activities of the newer task forces set up to meet specific problems:

EYE AREA SAFETY: This task force has drafted proposals aimed at minimizing potential risks to consumers through misuse of eye area cosmetic products. The task force is also initiating round-robin testing of methodology involving FDA and Dr. Louis Wilson, an ophthalmologist under contract to FDA.
GMP's: A good manufacturing practices task force has prepared comments on the proposed drug GMP's and will meet with FDA to discuss FDA plans for publishing cosmetic GMP's.
GLP's: A good laboratory practice task force has drafted comments for submission to FDA by the March 21 deadline.

Talc: A task force has just concluded a round-robin test of methodology for detection of asbestos with FDA and Mt. Sinai Hospital scientists. This methodology has just been published by CTFA as part of a revised Standard for Talc. The results of the study are expected to affirm the purity of current talcum products.

OTC Panel Reviews: CTFA has several active OTC task forces open to all interested manufacturers and suppliers. The OTC panels have been occupied since January 1, 1977 on learning how to live with "open meetings" under the new Sunshine Law. Panels of concern to our industry are:

antiperspirant
oral cavity
topical analgesic
miscellaneous external
dentrifice
and antimicrobial II

Contact Jim McNerney of CTFA staff if you have questions in any of these areas.

CTFA is also active in the safety research area. Murray Berdick will discuss color additive testing requirements in a few moments. In addition, CTFA has initiated Phase III of its long-term studies on temporary semi-permanent and oxidation-type hair dyes, and, through the Inter-Industry Aerosol Safety Committee, is completing design of protocols for testing particulate ingredients as well as its exploration of possible alternative propellants.

SAC Organization: Finally the Scientific Advisory Committee, the body that coordinates the activities of the scientific department, is undergoing a further reorganization designed to ensure efficient handling of scientific programs. You may recall that the first phase of the reorganization opened up membership on the scientific advisory committee to all chief scientists of active member companies. That change considerably strength-

Microbiology
Frank Wertalik
Schering-Plough

I'd like to go through some of the activities of the subcommittees and task forces of the Microbiology Committee.

They have a joint CTFA Mutagenicity Task Force with the CTFA Pharmacology and Toxicology Committee. The joint committee was formed in 1977 to review, evaluate, report on published and unpublished testing methods and scientific information.

The Eye Area Safety Task Force, an industry task force was formed in 1977 to review this area. The task force membership is technically diversified and affords an excellent cross-section of management for full development of each selected topic.

The Microbiological Methods Task Force was formed to develop more uniform microbiological methods for the evaluation of materials. We have been working on a revision of the Microbiological Guidelines for Process Water, recognizing new technical information, developments and advancements.

We have the "Microbiological Forum." I'm Chairman of the Information Education Subcommittee, and the "Forum" is one of the things that we use. It's a very important vehicle. We'd like more contribution from the membership. The "Forum" is in the *CTFA Cosmetic Journal*, and includes short articles relating to the field of microbiology.

We have produced a new slide-tape presentation entitled, "Cleaning and Sanitation of Manufacturing Equipment." We have continued our efforts for informing and educating industry members by completing this fifth slide-tape presentation.

We are developing a poster series. Two of the posters are posted at the exhibit booth, in rough form. The Committee has in mind a series of posters for plant and personal hygiene for the manufacture of high-microbiological quality cosmetics.

We're planning a workshop on decontamination technology and sanitization technology in April. We have some information at the booth on that.

We have developed the Microbiological Guidelines for Sampling Cosmetic Raw Materials both in process and finished goods. This guideline has been approved and should be published in the near future. We have developed the microbiological aspects of quality assurance, which has been updated, and the guidelines for cleaning and sanitization of equipment are in developmental stages. Guidelines for evaluating shelf life stability of product preservation systems are under discussion. Determination of a panel selection and product testing protocols for *in-vitro* and *in-vivo* correlation testing are being discussed for performing this correlation evaluation.

On October 10, 1976, the present CTFA Standard for Cosmetic Talc was published. It marked a notable step forward in controlling the quality of the talc used by the CTFA membership, by guarding against the presence of asbestiform impurities in the talc products sold by CTFA membership. As a result of the efforts of the ad hoc Methodology Committee under the chairmanship of Dr. Robert Rolle, it reflects the most up-to-date technology available in the greatest number of laboratories available to the CTFA membership. It also utilizes the largest and most significant sample size of any method for the evaluation of a talc shipment which may be small, or carload in size.

REDACTED

Talc Subcommittee
George Sandland
Bristol-Myers Company

The new Cosmetic Talc Standard is a modification of the old TGA/CTFA Talc Standard with the following major additions:

1. An Optional identification procedure using X-ray diffraction.
2. The addition of a "none detected" limit for fibrous amphiboles, using CTFA Method J 4-1. In this method, the following steps are required:
   (a) A primary detection of amphiboles by X-ray diffraction, is employed as the first step.
   (b) When a positive detection of amphiboles is indicated, a secondary procedure using light microscopy along with dispersion staining is applied to determine whether or not any amphiboles

detected by X-ray diffraction are asbestiform in nature.

3. Optional procedures are given for the estimation of quartz or crystalline silica:
   (a) Method J 5-1, using DTA, is capable of detecting 0.5 to 1.0% of quartz.
   (b) Optional Method J 6-1, using X-ray diffraction, is capable of detecting 2.0% of quartz.

A round robin was conducted early this year using Method J 4-1 on samples from seven different brands representing 90% of the sales volume of talcum products on the market. The results showed inconsistencies of data among some of the participants, particularly in the use of the Part II Optical Microscopy and Dispersion Staining Method. Because of this, a more comprehensive version of the optical method was written. It has been sent to all participants for a second round robin, along with another set of controls plus those samples from the market which seemed to be associated with the inconsistent data. As of this writing, the testing is incomplete.

It must be emphasized that the Optical Microscopic Method Part II section of Method J 4-1 is not an easy procedure. It requires the expertise of a very competent microscopist, who also has experience in mineralogy. Since scientists meeting these qualifications are not numerous, we are considering a program under the sponsorship of CTFA, designed to train microscopists specifically in the required discipline.

In the meantime, we have every confidence that Method J 4-1 is practical, and can be successfully used by properly trained scientists.

Our future plans include a refinement of the optical microscope procedure to make it usable by as many scientists as possible.

Now for just a few points of interest:

A Workship on Asbestos was conducted on July 18 to 20, 1977, at the National Bureau of Standards. Close to 400 participants, primarily from industry, government agencies and the research community, attended.

The workship did not result in recommendations for the definition and measurement of asbestos, which may be correlated with biological activity. There was overwhelming opinion that there is a dose-effect relationship for asbestos and an expected threshold. Without doubt, if there were agreement as to a definition of asbestos for regulatory purposes, there are techniques for detection and quantitation. However, some of these techniques are extremely sophisticated, require highly specialized training, are research-based, and are impractical for routine control purposes.

There were no allegations against the safety of cosmetic talc, however, the Food and Drug Administration expects to promulgate regulations for cosmetic talc in the future, to guard against the use of impropoer talcs for cosmetic purposes.

The history of use of cosmetic talc indicates that it is safe, and it has been placed in Category I for efficacy and safety by the OTC Antimicrobial II and External Products Panels.

I wish to extend sincere thanks to Dr. F.R. Rolle who served as Chairman of the ad hoc Talc Methodology Committee and to Dr. J.P. Schelz, Chairman of the CTFA Talc Task Force. We are also grateful for the time and effort put forth by members of the Food and Drug Administration, of the academia, and of industry, to assist in this important project.

Last year at this time, CTFA had submitted the galley proofs of the second edition of the *CTFA Cosmetic Ingredient Dictionary* to the FDA and received some recommendations from them for changes. To a large extent, we modified various CTFA Adopted Names and monographs to conform with their suggestions in March of this year, the second edition was published. The *Dictionary* has been well received. Over 3,000 copies have been sold both here and abroad.

Nomenclature

Griffin Shay
Avon Products, Inc.

In the October issue of *Cosmetics and Toiletries* Ed DeNavarre gave the *Dictionary* a generally positive review. Other reviewers have been equally complimentary.

On Friday, October 28, FDA proposed to recognize the second edition of the *Dictionary*, providing 60 days for comment. There are a number of ingredients for which FDA feels the monographs in the *Dictionary* disclose neither the chemical configurations nor, where appropriate, the substances of origin. FDA has proposed continued adoption of the names for some