

MEMORANDUM OF
TELEPHONE CONVERSATION

DATE: 5/18/92

BETWEEN: Name: Jim Skiles
Affiliation: CTFA
Phone: 202-331-1770

AND: Jeanne L. Rippere
HFD-213

SUBJECT: Sunscreen Products - Drug/Cosmetic Proportions

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Last week I called Mr. Skiles to ask if they have an estimate of the number of cosmetic products that contain sunscreens. If yes, do they have a listing of who makes them? Mr. Skiles was on vacation, but I was told that Kathy Beckley might be able to help. Ms. Beckley said that she would look around and see what she could come up with. Mr. Skiles called to say that he had some limited information, but no good answers. He said that the best place to look would be FDA's Voluntary Listing Program. He also said that there are approximately 14,000 products containing sunscreens. (He said that the number is increasing daily so that figure is out of date, but it is as good as estimate as anything.)

Mr. Skiles also noted that there are really 3 classes of products -- (1) beach, (2) non-beach, and (3) an intermediate, overlapping class of products that are marketed for both places. He mentioned a product that is marketed as a cosmetic but is clearly intended for use on the beach also. I wondered whether the company manufacturing that product follows drug CGMP's. He said yes and added that most cosmetic manufacturers have drug CGMP's in place because they already manufacture anti-perspirants, skin protectants, and other products that are drugs. If they don't have the facilities, they contract them out.

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cc: HFD-210:DDC-940.3/Reading/Deputy
HFD-213:(Sunscreen TFM):Rippere **G.R. 5-18-92**

TELEPHONE CONVERSATION

DATE: 9/27/89

WEEEN:

Name: Harold E. Seifried

Affiliation Technical Resources, Inc./Tractor
Technology Resources, Inc.

Phone ?

AND

Your name: Jeanne Rippere
Division of OTC Drug Evaluation (HFN-210)

SUBJECT: NPABAO in Padimate O

DISCUSSION:

Dr. Seifried's company is evaluating the potential mutagenicity and carcinogenicity under contract to National Cancer Institute as part of the National Toxicity Program. One of the ingredients that they are looking at is Padimate O/NPABAO. He called me to tell me that NPABAO tested negative in its first run through the battery of tests they use to determine mutagenicity. He said that they were going to run it through again in another solvent to corroborate the first tests. He promised to send a copy of their report as as soon as it is available (it is public information and may be put into the administrative record). He also said that they hadn't been able to use CFSAN's method for synthesizing NPABAO and had to develop their own. He said that he would keep me apprised of their progress. I thanked him, and the call ended.

JR
10/3/89

cc: HFD-210: DDC940.3/Reading/Deputy

HFD-213: (sunscreen): Chief/Rippere

TELEPHONE CONVERSATION

DATE: 5/15/89

BETWEEN:

Name: John Clayton

Affiliation: Plough

Phone: (901) 320-2917

AND

Your name: Jeanne Rippere

Division of OTC Drug Evaluation (HFN-210)

SUBJECT: Sunscreen Labeling

DISCUSSION:

I contacted Dr. Clayton to request representative labeling from Plough's sunscreen products. I told him that I was interested in examples of available labeling for products with various SPF values, for products with different combinations of sunscreens, for tanning preparation, with and without sunscreens, for tanning accelerator products, and for "broad spectrum" products. He said that he would assemble copies of pertinent sunscreen labeling and send it to me. I thanked him and the conversation ended.

cc: HFD-210: DDC 940.3/Reading/Deputy

HFD-213: (Sunscreen TFM): Chief/Rippere

agf

TELEPHONE CONVERSATION

DATE: 5/15/89

BETWEEN:

Name: Tom Koestler

Affiliation: Westwood

Phone: (716) 887-3583

AND

Your name: Jeanne Rippere

Division of OTC Drug Evaluation (HFN-210)

SUBJECT: Sunscreen Labeling

DISCUSSION:

I contacted Mr. Koestler to request representative labeling from Westwood's sunscreen products. I told him that I was interested in examples of available labeling for products with various SPF values, for products with different combinations of sunscreens, for tanning preparation, with and without sunscreens, for tanning accelerator products, and for "broad spectrum" products. He said that he would assemble copies of pertinent sunscreen labeling and send it to me. I thanked him and the conversation ended.

cc: HFD-210: DDC 940.3/Reading/Deputy

HFD-213: (Sunscreen TFM): Chief/Rippere

afm

TELEPHONE CONVERSATION

DATE: 5/11/89

BETWEEN:

Name: Marjorie McTernan

Affiliation: Johnson and Johnson

Phone: (201) 874-1326

AND

Your name: Jeanne Rippere

Division of OTC Drug Evaluation (HFN-210)

SUBJECT: Sunscreen Labeling

DISCUSSION:

I contacted Ms. McTernan to request representative labeling from Johnson and Johnson's sunscreen products. I told her that I was interested in examples of available labeling for products with various SPF values, for products with different combinations of sunscreens, for tanning preparation, with and without sunscreens, for tanning accelerator products, and for "broad spectrum" products. She said that she would assemble copies of pertinent sunscreen labeling and send it to me. I thanked her and the conversation ended.

cc: HFD-210: DDC 940.3/Reading/Deputy

HFD-213: (Sunscreen TFM): Chief/Rippere

ajr

MEMORANDUM



TELEPHONE CONVERSATION



MEMORANDUM OF A MEETING

DATE: May 6, 1988

BETWEEN:

Name: Dr. Kay Kaidbey
Affiliation: Sun Laboratories
Phone: (215) 387-8400

AND

Your name: Jeanne Levine
Division of OTC Drug Evaluation (HFN-210)

SUBJECT: Phototoxicity of Padimate A -

DISCUSSION:

I called Dr. Kaidbey to discuss the phototoxicity of Padimate A which is the subject of one of the Sunscreen TFM issues. Dr. Kaidbey and Kligman published a paper in 1978 documenting the phototoxicity of this sunscreen ingredient, and submitted a comment to the sunscreen rulemaking. I asked Dr. Kaidbey if he was aware of any follow-up studies on the phototoxicity of Padimate A or if there were any more recent reports in the literature. He said that he wasn't aware of anything more recent, and that the subject had sort of "fallen by the wayside" because most companies had stopped using the ingredient. He said that he wasn't aware of any company currently using the ingredient in any sunscreen product. I thanked him, and the call ended.

JL
5/6/88

cc: HFN-210: DOC 940.3 /Reading/Depu

MEMORANDUM

TELEPHONE CONVERSATION

MEMORANDUM OF A MEETING

DATE: April 8, 1988

BETWEEN:

Name: Marsha Hardner

Affiliation: CTFA

Phone: (202) 331-1770

AND

Your name: Juanne Lopez
Division of OTC Drug Evaluation (HFN-210)

SUBJECT: Sunscreen Testing Procedures Meeting
Extension of Comment Period

DISCUSSION: Ms. Hardner called to ask if ODE would be receptive to a request to extend the comment period for the sunscreen meeting for 30 days. She said that the CTFA statisticians would not have their reports done in time for the April 22 closing date. I told her that I didn't foresee any problem with an extension. She answered that CTFA would submit a request soon.

She then asked if we had given any thought to having OEP handle the sunscreen standard formulations (including a possible high SPF formula). She said that several companies were interested in developing standard, but nobody wanted to be responsible for handling the standard afterwards (apparently Schering-Plough agreed to handle the 8% homologous standard and has regretted it ever since). I said that we really hadn't considered that, but that we would think about it.

She thanked me for my time, and the conversation ended.

Memorandum of Telephone Conversation
October 8, 1986

Between: Dr. Joseph Stanfield
Westwood Pharmaceuticals Inc.
(716) 887-3583

and

Catherine Sullivan
Division of OTC Drug Evaluation (HFN-213)

Subject: Survey for Sunscreen SPF Testing

Discussion: Background: See the memorandum of the telephone conversation with Lorraine Cowton of Avon Products, Inc., September 24, 1986, for the three questions asked.

The following are Dr. Stanfield's answers to the survey questions:

- 1) For the last several years, they have used indoor testing exclusively.
- 2) They use indoor testing because they get a more reliable measure of the energy dose used in the SPF determinations. Indoor testing is much easier to control and much less expensive. It is also very difficult to get 12 or 15 MEDs of UV radiation from natural sunlight in one day in order to measure the high SPF products.
- 3) They have two light sources, a Kratos 2500 watt zenon arc and a 150 watt zenon arc from Solar Light Co. in Philadelphia. Both comply with the Panel's recommendations.

Catherine Sullivan
Catherine Sullivan

cc: HFN-210:DDC-940.3/Reading/Rachanow
HFN-213:Sunscreen TFM/Bader/Sullivan

Memorandum of Telephone Conversation
September 25, 1986

Between: Dr. Donald Jones
Johnson & Johnson Products, Inc.
(201) 874-1498

and

Catherine Sullivan
Division of OTC Drug Evaluation (HFN-213)

Subject: Survey for Sunscreen SPF Testing

Discussion:

Background: See the memorandum of telephone conversation with Lorraine Cowton of Avon Products, Inc. September 24, 1986, for the three questions asked.

The following are Dr. Jones' responses to the three questions:

- 1) Dr. Jones said that they primarily use indoor testing for SPF determinations. They have tried outdoor testing, but it is impossible to control.
- 2) They use indoor testing because of the variability of conditions outdoors. The sun is different from one time of day to another, from day to day, and from week to week. He finds that you cannot control the tests adequately even doing them side-by-side outdoors.
- 3) A Berger solar simulator, 150 watt zenon arc lamp with a WG320-1mm filter is the light source used at Johnson & Johnson. It conforms to the Panel's recommended specifications.

Catherine Sullivan

Catherine Sullivan

cc: HFN-210/DDC-940.3/Reading/Rachanow
HFN-213/Sunscreen TFM/Bader/Sullivan

Memorandum of Telephone Conversation
September 29, 1986

Between: Dr. Ward Billheimer
Hilltop Research Laboratories, Miamiville, OH
(513) 831-3114

and

Catherine Sullivan
Division of OTC Drug Evaluation (HFN-213)

Subject: Survey for Sunscreen SPF Testing

Discussion:

Background: See the memorandum of telephone conversation with Lorraine Cowton of Avon Products, Inc. September 24, 1986 for the three questions asked.

The following are Dr. Billheimer's responses to the three questions:

1) Dr. Billheimer said they basically use only indoor testing. They did one outdoor test in Arizona and at a research project in Cincinnati, but they do not have a lot of experience with outdoor testing. Before the Panel's report was published, they were gearing up for outdoor SPF testing because they thought that it would be required.

2) They use indoor testing because it is very much easier to control--no clouds, pollution, rain, and because a product with a high SPF (15 and above) cannot be determined outside (not enough sunlight in one day). He said that there have been 1 or 2 investigators who have claimed to do it, but one needs ideal conditions.

3) They have a Kratos 1000 watt xenon arc solar simulator obtained from Kratos Analytical in Ramsay, N.J. The main difference between this and the Berger 150 watt source is that the 150 watt has only a 1 cm beam of light, enough for one determination whereas with the higher power, larger beam, they can do 4 SPF determinations simultaneously. The light source complies with the Panel's recommendations.

Catherine Sullivan
Catherine Sullivan

cc: HFN-210/DDC-940.3/Reading/Rachanow
HFN-213/Sunscreen TFM/Bader/Sullivan

MEMORANDUM OF A TELEPHONE CONVERSATION

September 25, 1986

BETWEEN: Joanne Nikitakis, The Cosmetic, Toiletry,
and Fragrance Association (CTFA)
331-1770

AND

Catherine Sullivan, Eye, Ear, Nose,
Throat and Oral Cavity (HFN-213)
Division of OTC Drug Evaluation

SUBJECT: CTFA Names for Sunscreen Ingredients

Background: I called the CTFA in order to find out what the current CTFA name for aminobenzoic acid is and also to ask why they don't use the name aminobenzoic acid which has been recognized as the established drug name for 20 years.

Ms. Nikitakis told me that the CTFA name for aminobenzoic acid is PABA. She said that the CTFA names are to be used for cosmetic labeling and that the USAN names are to be used for drug labeling. She said that they use the abbreviation PABA in cosmetic labeling because it is shorter and is recognizable to consumers as a sunscreen.

I asked what the CTFA names for Padimate A and Padimate O are. Padimate O is octyl dimethyl PABA, and there is no CTFA name for Padimate A because no cosmetic company submitted the ingredient to the CTFA.

Catherine Sullivan

cc: HFN-210: DDC 940.3/Reading/Deputy
HFN-213: Sunscreen TFM/Bader/Sullivan
RD:CSullivan/lj/9/30/86
FT:ljones/9/30/86
DOC ID 0255G/DISKETTE 0069G (#2)

CCJ
9/30/86
S. Bader 9/30/86

G.R. 9-30-86

Memorandum of Telephone Conversation
September 24, 1986

Between: Ms. Lorraine Cowton
Avon Products, Inc., Suffern, NY
(914) 357-2000

and

Catherine Sullivan
Division of OTC Drug Evaluation (HFN-213)

Subject: Survey for Sunscreen SPF Testing

Discussion:

Background: Using the names of the major SPF testing facilities provided by Emmalee Murphy of the Cosmetic, Toiletry, and Fragrance Association (CTFA) (see telephone memorandum of September 11, 1986), I conducted a telephone survey to determine the current state of the art of sunscreen SPF testing. I asked three questions.

Q. 1) Do you use indoor or outdoor testing?; 2) If you only use indoor, why?; 3) What kind of solar simulator do you use for indoor testing?

Ms. Cowton performs the SPF tests at Avon. The following are her responses to the above 3 questions:

A. 1) Only indoor testing is used.

2) It takes less time than outdoor testing, is more reproducible, and can be done year round.

3) 150 watt xenon arc solar simulator with a 1mm Schott WG320 filter, reflecting dichroic mirror, 1mm UG-11 filter (removes reflected heat) is used. This light source was purchased from Daniel Berger, Solar Light Co., Philadelphia, PA. The light source conforms to the Panel's recommended specifications.

Catherine Sullivan

Catherine Sullivan

cc: HFN-210/DDC-940.3/Reading/Rachanow
HFN-213/Sunscreen TFM/Bader/Sullivan

Memorandum of Telephone Conversation
September 24, 1986

Between: Dr. Robert Sayre
Plough, Inc., Memphis, TN
(901) 320-2011

and

Catherine Sullivan
Division of OTC Drug Evaluation (HFN-213)

Subject: Survey for Sunscreen SPF Testing

Discussion:

Background: See memorandum of telephone conversation with Lorraine Cowton, Avon Products, Inc., on September 24, 1986. I asked Dr. Sayre the following three questions:

Q. 1) Do you use indoor or outdoor testing?

A. 1) He said they use primarily indoor testing and do about 3000 determinations per year. He has done outdoor testing in the past and published a paper comparing outdoor and indoor testing but is sure that they have done no outdoor testing this year.

Q. 2) Why do you use primarily indoor testing?

A. 2a) Because you can control the conditions. Outdoor testing is extremely difficult to control and is not reproducible.

2b) There is not enough sun in one day to test the products with higher SPF's.

2c) In sunlight, the whole body is at risk and exposed. The subjects must be still for a very long time whereas indoor light sources expose only small areas of the body for shorter time periods. Outdoor tests require as many clinical assistants as subjects.

Q. 3) What is your light source?

A. 3) A 2500 watt xenon arc solar simulator with a Berger-type design that I built myself. An innovation in this system is a continuous computer-controlled monitoring of the entire system. The light source conforms to the Panel's recommended specifications.

Catherine Sullivan

Catherine Sullivan

cc: HFN-210; DDC-940.3/Reading/Rachanow
HFN-213; Sunscreen TFM/Bader/Sullivan

Memorandum of Telephone Conversation
September 12, 1986

Between: Dr. Kays Kaidby
Ivy Laboratories, Philadelphia, PA
(215) 387-8400

and

Catherine Sullivan
Division of OTC Drug Evaluation (HFN-213)

Subject: Sunscreen SPF Testing

Discussion:

Background: See memorandum of telephone conversation with Emmalee Murphy of Cosmetic, Toiletry, and Fragrance Association on September 11, 1986. I called Ivy Laboratories to see if they would be willing to demonstrate their sunscreen SPF testing procedures for some of the FDA employees and also to ask if they were doing indoor or outdoor sunscreen SPF testing.

Kays Kaidby of Ivy Laboratories said that he would welcome a visit from the FDA and that he would send us the protocol that they use for SPF testing and other relevant literature.

When asked about the testing, he replied that they always use indoor testing and perform it in accordance with the Panel's report.

I told him that we would get back to him after we receive his literature.

Catherine Sullivan

Catherine Sullivan

cc: HFN-210; DDC-940.3/Reading/Rachanow
HFN-213; Sunscreen TFM/Bader/Sullivan