



April 27, 1979

Office of the Hearing Clerk (HFA-305)
Food and Drug Administration
Room 4-65
5600 Fishers Lane
Rockville, Maryland 20857

RE: Establishment of a Monograph; Notice of Proposed Rulemaking, Skin Bleaching Drug Products for Over-the-Counter Human Use ((43 Federal Register 51546 (November 3, 1978)) (Docket No. 78N-0065).

Dear Sir:

On January 24, 1979 Elder submitted comments and recommendations for consideration by the Commissioner of Food and Drugs with respect to the above-referenced proposal. Recommendation II in the January 24 letter read as follows:

IT IS RECOMMENDED THAT THE PROPOSED SECTION 21 CFR 358.20 BE EXPANDED TO INCLUDE HYDROQUINONE FORMULATIONS IN A BASE OPAQUE TO ULTRAVIOLET RADIATION.

I now wish to submit clinical evidence to demonstrate that the Elder skin bleaching drug products, ELDOPAQUE and ELDOPAQUE-FORTE, which contain 2% and 4% Hydroquinone, respectively, are combined with a safe and effective sunscreen active ingredient and therefore, should be classified as products with permitted combination of active ingredients under the Proposed Section 21 CFR 358.20. The safe and effective sunscreen active ingredient with which hydroquinone is combined in our products, ELDOPAQUE and ELDOPAQUE-FORTE is a hydrophilic, opaque base containing 10% talc as a light scattering and reflecting agent. The Proposed Regulation 21 CFR 352 - Sunscreen Products for Over-the-Counter Human Use, Section 352.43 specifies the testing procedure for the determination of the Sun Protection Factor (SPF) value using an artificial light source. The SPF values of ELDOPAQUE and ELDOPAQUE-FORTE have been determined according to this procedure, using 20 subjects for each product by Dr. Isaac Willis. The SPF value for ELDOPAQUE is 8.95 and the SPF value for ELDOPAQUE-FORTE is 8.90. These determinations were carried out under the supervision of Dr. Isaac Willis, Suite 275, Buckhead Medical Building, 3312 Piedmont Road, N.E., Atlanta, Georgia 30305. Copies of the data charts for 20 patients for each product, as compiled by Dr. Willis, are attached to this letter.

The present wording of the Proposed Section 21 CFR 358.20 specifies only sunscreens as defined in the Proposed CFR 352.10. In Section 352.10 is an approved list of sunscreen active ingredients when they are used in such a manner that the finished product provides a minimum SPF value of not less

78N-0065

00001

Manufacturers • Paul B. Elder Company • 705 East Mulberry Street • P.O. Box 31 • Bryan, Ohio 43506
(419) 636-1168 • Toll Free (800) 537-4294 • (800) 537-4295

Distributors • Thomas C. Elder, Inc. • P.O. Box 125 • Hamilton, Indiana 46742 (219) 488-3293

Page #2
April 27, 1979
Office of Hearing Clerk

than 2 as measured by the testing procedure referenced above and used by Dr. Willis. We wish to make the point that the Proposed Regulation 21 CFR 352 of which the Proposed Section 352.10 is a part, was developed by an Advisory Review Panel that considered only products for which the sunscreen indication is the primary claim and did not consider non-transparent opaque bases such as are used in cosmetic formulations.

Since we have demonstrated that our products, ELDOPAQUE and ELDOPAQUE-FORTE have SPF values more than 4 times the minimum required in Proposed Section 352.10 for sunscreen active ingredients, we recommend that the language of Proposed Section 21 CFR 358.20 be expanded to include hydroquinone combinations with a base opaque to ultraviolet radiation.

Further, we recommend that Elder products, ELDOPAQUE and ELDOPAQUE-FORTE, be specifically included among the permitted combinations of Proposed Section 21 CFR 358.20.

The opportunity to be permitted to present these comments is appreciated. They are submitted in quadruplicate.

Sincerely,



Richard N. Hurd, Ph.D.
Vice President of Technical Affairs

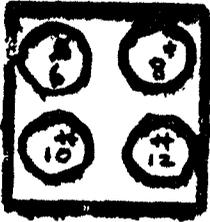
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enclosures: data charts

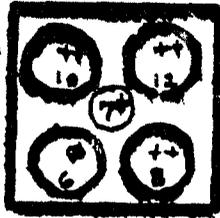
cc: Mr. John McElroy, FDA
Mr. A. Young
Mr. A. Boschetti
Mr. T. Elder
Mr. D. Weilbaker
Dr. I. Willis

SUNSCREEN EVALUATION
by Isaac Willis, M.D.

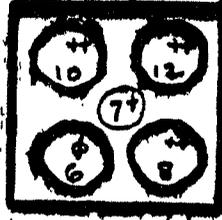
SUNSCREEN # ELDOPTAQUE
SUBJECTS TESTED 20



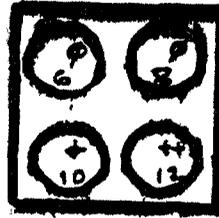
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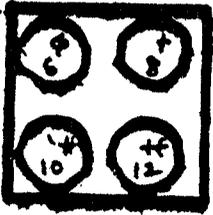
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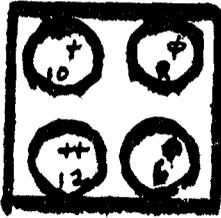
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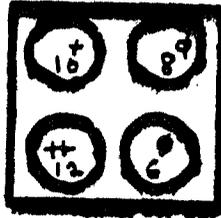
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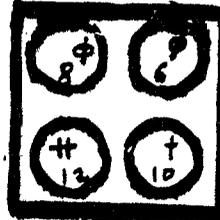
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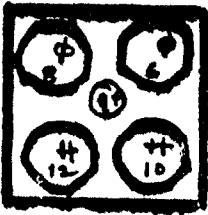
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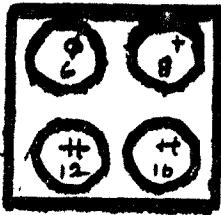
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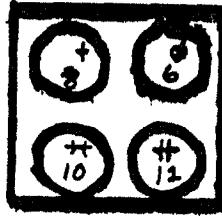
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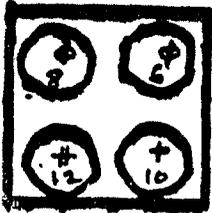
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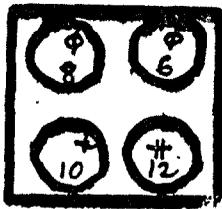
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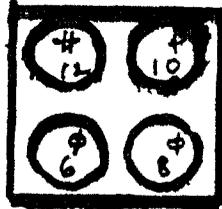
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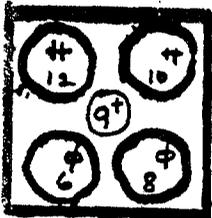
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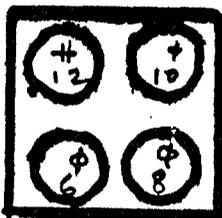
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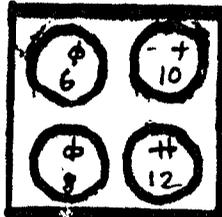
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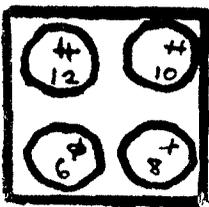
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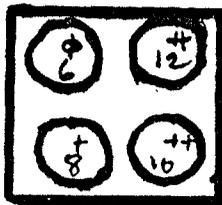
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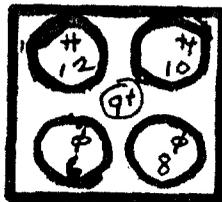
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#18



#19



#20

SPF VALUES

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3	<u>7</u>
4	<u>10</u>
5	<u>8</u>
6	<u>10</u>
7	<u>10</u>
8	<u>10</u>
9	<u>9</u>
10	<u>8</u>
11	<u>8</u>
12	<u>10</u>
13	<u>10</u>
14	<u>10</u>
15	<u>9</u>
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17	<u>10</u>
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19	<u>8</u>
20	<u>9</u>

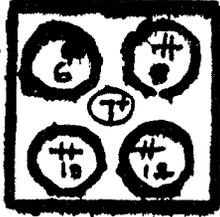
AVERAGE SPF = 8.95

UNSCREEN EVALUATION
by Isaac Willis, M.D.

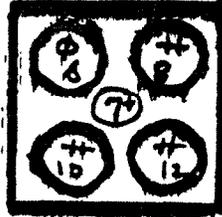
SUNSCREEN # ELDERBERRY FORTS
SUBJECTS TESTED 20



#1



#2



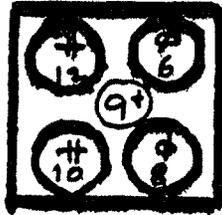
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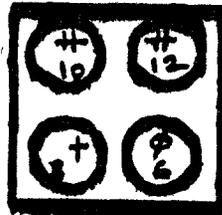
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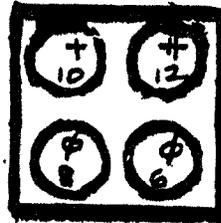
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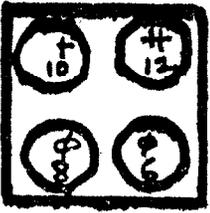
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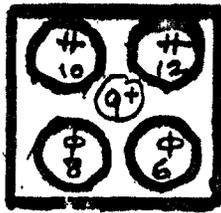
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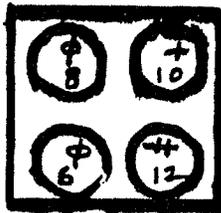
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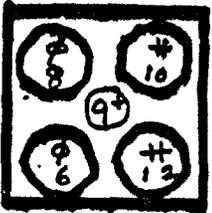
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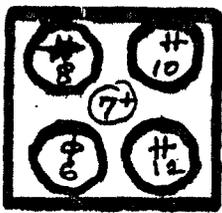
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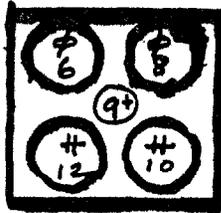
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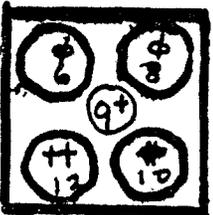
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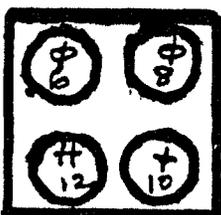
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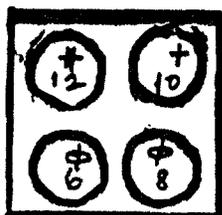
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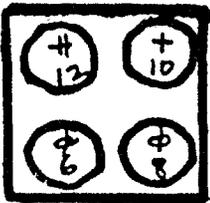
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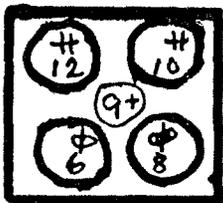
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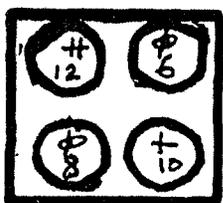
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#18



#19



#20

SPF VALUES

SUBJECT 1	<u>7</u>
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3	<u>7</u>
4	<u>9</u>
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6	<u>9</u>
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13	<u>7</u>
14	<u>9</u>
15	<u>9</u>
16	<u>10</u>
17	<u>10</u>
18	<u>10</u>
19	<u>9</u>
20	<u>10</u>

AVERAGE SPF = 8.9