MEMORANDUM OF A MEETING

April 11, 1984

1984 APR 10 PM 12:47

ATTENDEES: See attached list.

SUBJECT: Phenylpropanolamine -- Feedback Information

The Ciba-Geigy Corporation requested this meeting in order to present data obtained from market research on appetite suppressants and to discuss details of phenylpropanolamine dose-response protocols.

Dr. Gilbertson opened the meeting by stating that the agency considers this to be a feedback meeting and, therefore, open to the public. He further stated that the agency has not yet received any submissions of data in response to requests made at the December 2, 1983 meeting. At that meeting the agency requested a compilation of phenylpropanolamine-related adverse reactions and proposed protocols of studies which would demonstrate the dose-response relationship between phenylpropanolamine and its hemodynamic effects.

Mr. Jeff Lyle from Ciba-Geigy presented data from a market research study (National Analysts Study) demonstrating: (1) that a very small portion of those taking appetite suppressants are severly overweight, (2) that a very large percentage (89% in this study) of women taking appetite suppressants are 44 years of age or younger, and (3) that those taking appetite suppressants represent a small proportion (25.6% in this study) of all hypertensives based on national incidence figures. (See attachments.)

Dr. Thomas Garvey, a consultant for Ciba-Geigy, discussed the concepts of phenylpropanolamine dose-response studies which Ciba-Geigy intends to conduct. There was a general consensus among the Ciba-Geigy representatives and FDA personnel that there is a definite need to first define the shape of a phenylpropanolamine dose-response hemodynamic curve in normals. When that is accomplished, outlyers would be identified and a determination can be made as to what further studies are necessary. Ciba-Geigy agreed to generate a protocol for the study in normals and submit it to the agency as soon as possible for comment.

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Dr. Edward Steinberg (Thompson Medical Company), an observer at the meeting, volunteered that Thompson has completed a tabulation and analysis of all published adverse reactions involving phenylpropanolamine and intends to submit it to the agency within one week. He said that Thompson is also working on a protocol for a dose-response study and will submit it to the agency for comment very shortly.

Dr. Garvey also commented that Ciba-Geigy has submitted an FOI request to obtain all Form 1639s relative to phenylpropanolamine adverse reactions. Following receipt, he intends to analyze the data to see what conclusions can be reached regarding further development of phenylpropanolamine studies.

Mr. Robert Pinco, consultant for Ciba-Geigy, concluded with a summation of what transpired during the meeting and made the comment that he hopes that there would be no precipitous regulatory action which would prevent Ciba-Geigy from performing their anticipated studies.

John R. Short

John R. Short

Attachments (3)

ATTENDEES

FDA Personnel

Raymond Lipicky, M.D. (HFN-110)
Philip Dern, M.D. (HFN-110)
William E. Gilbertson, Pharm. D. (HFN-210)
Dennis L. Myers, R.Ph. (HFN-214)
John R. Short, R.Ph. (HFN-214)

AND

Industry And Press

Patrick E. Ciccone, M.D., Menley and James
Thomas E. Costa, Esq., A. H. Robins
Thomas Q. Garvey, M.D., Garvey Associates, Inc.
Eric Katz, Esq., Kay, Scholer, Fierman, Hays, and Handler
Jeff Lyle, Ciba-Geigy
Emily Morley, M.D., A. H. Robins
Gerald Ostrov, Ciba-Geigy
Robert Pinco, Esq., Perito, Duerk and Pinco
Raymond Ragland, Ph. D., Menley and James
Brenda Sandburg, F-D-C Reports
Eric Siegel, M.D., The Proprietary Association
Edward Steinberg, O.D., Thompson Medical
Dorothy Watson, Esq., Ciba-Geigy

RAW WEIGHT DISTRIBUTION OF RESPONDENTS*
(National Analysts Study)

Actual - Ideal (lbs.)	Number	%	Cumulative %
-11 and under	4	1	1
-10 to - 6	12	3	4
- 5 to - 1	15	4	8
0 (within range)	98	27	35
+ 1 to + 5	38	10	45
+ 6 to +10	37	10	55
+11 to +15	24	7	62
+16 to +20	17	5	67
+21 to +30	34	9	76
+31 to +40	25	7	83
+41 to +50	20	6	89
+51 and over	38	11	100
	362	100	

*compares actual weight in pounds to "ideal" weight from 1983 Metropolitan Life Tables, based on height and age

RAW AGE DISTRIBUTION OF RESPONDENTS*
(National Analysts Study)

Age	Appetite Suppressant User %	Cumulative %	U.S.** Adult Female Population %	Cumulative %
18-24 yrs.	22	22	17	17
25-34 yrs.	40	62	23	40
35-44 yrs.	27	89	16	56
45-54 yrs.	9	98	13	69
55-64 yrs.	2	100	13	82
65 or older	0	100	18	100
	100		100	

* Sample of 459 appetite suppressant users.

** U.S. Department of Commerce, Bureau of Census, 1982 projection.

HYPERTENSION AMONG U.S. FEMALES
Age 25 or Older

Age	Number of Hypertensive Females (millions) *	Rate of Hypertension In Age Group %
25-34 yrs.	.9	4.6
35-44 yrs.	1.7	11.9
45-64 yrs.	6.7	28.7
65 or older	6.9	43.0

* American Heart Association, 1981.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Dockets Management Branch (HFA-305) DATE: APR 18 [redacted]

FROM : Director
Division of OTC Drug Evaluation (HFN-510)

SUBJECT: Material for Docket No. 81N-0022 + 76N-052N

☑ The attached material should be placed on public display under the above referenced Docket No.

☐ This material should be cross-referenced to Comment _____.

William E. Gilbertson, Pharm. D.

Attachment