C O N F I D E N T I A L

TITLE — SANTICIZERS 409 AND 411 INCREASED PROFITS FROM FDA APPROVAL

INTRODUCTION - An examination of the possibility for obtaining FDA acceptance on Santicizers 409 and 411 was made in 1965. Metabolic studies were conducted but the results were not definite enough for the FDA to grant approval. FDA has requested two year oral feeding studies before they can give their acceptance.

This report shows the extra business that is obtainable by having FDA approval and the increase in gross profit after running the feeding tests and subsequently obtaining the approval.

SUMMARY AND CONCLUSIONS - A field survey was made in 1965 to determine the value of having FDA approval on these two polymeric plasticizers. The survey developed enough information to justify the two year feeding studies.

Sales of Santicizers 409 and 411 are expected to be 7.2M lbs. in 1972 without FDA approval with total dollar sales $2.3M, with gross profit of $601,000. With FDA approval total sales are expected to be 9.5M lbs. in 1972 with total dollar sales at $3.0M and gross profit up to $810,000.

STLCOPCB4090989

Total cost for two year oral feeding studies is $90,000 to $100,000. In 1969, the first year after approval, gross profit will be increased by $79,000, and in 1970 it will increase by $196,000. Refer to tables below and on the following page.

Sales Without FDA Approval

	Sales (M lbs.)	Price	Amount	Cost of Goods Sold Amount	Gross Profit	% of Sales
1968						
S-409	3.2	36.5	$1,168,000	$800,000	$368,000	31
S-411	2.5	29.5	737,000	561,000	176,000	24
1969						
S-409	3.4	36.0	1,224,000	850,000	374,000	30.5
S-411	2.7	29.5	800,000	608,000	192,000	24
1970						
S-409	3.5	36.0	1,260,000	875,000	385,000	30.5
S-411	2.9	29.5	850,000	650,000	200,000	25
1971						
S-409	3.6	35.5	1,280,000	900,000	380,000	29.7
S-411	3.2	29.0	930,000	720,000	210,000	22.5
1972						
S-409	3.8	35.0	1,330,000	950,000	380,000	28.5
S-411	3.4	29.0	986,000	765,000	221,000	22.5

Sales With FDA Approval

1968						
S-409	3.2	36.5	$1,168,000	$800,000	$368,000	31
S-411	2.5	29.5	737,000	561,000	176,000	24
1969						
S-409	3.9	36.5	1,420,000	980,000	440,000	31
S-411	2.9	29.5	855,000	650,000	205,000	22
1970						
S-409	4.3	36.0	1,541,000	1,070,000	471,000	30.6
S-411	3.4	29.5	1,000,000	765,000	235,000	23.5
1971						
S-409	4.8	35.5	1,700,000	1,200,000	500,000	31.0
S-411	4.1	29.0	1,180,000	940,000	240,000	20.5
1972						
S-409	5.1	35.0	1,800,000	1,270,000	530,000	29.5
S-411	4.4	29.0	1,270,000	990,000	280,000	22.0

DSW 552573

STLCOPCB4090990

INCOME WITH AND WITHOUT FDA APPROVAL (in thousands)

	1967		1968		1969		1970		1971		1972	
	With Feeding Expense	Without Feeding Expense	With Feeding Expense	Without Feeding Expense	With FDA	Without FDA	With FDA	Without FDA	With FDA	Without FDA	With FDA	Without FDA
Net Sales	$1,754	$1,754	$1,905	$1,905	$2,275	$2,024	$2,541	$2,110	$2,880	$2,210	$3,070	$2,316
Cost of Goods Sold	1,241	1,241	1,361	1,361	1,630	1,458	1,835	1,525	2,140	1,620	2,260	1,715
Gross Profit	$ 513	$ 513	$ 544	$ 544	$ 645	$ 566	$ 706	$ 585	$ 740	$ 590	$ 810	$ 601
Less:												
SARE	$ 175	$ 175	$ 191	$ 191	$ 228	$ 202	$ 254	$ 211	$ 288	$ 221	$ 307	$ 232
FDA Feeding Test Expense	50		50									
	$ 225	$ 175	$ 241	$ 191	$ 228	$ 202	$ 254	$ 211	$ 288	$ 221	$ 307	$ 232
Income before Taxes	$ 288	$ 338	$ 303	$ 353	$ 417	$ 364	$ 452	$ 374	$ 452	$ 369	$ 503	$ 369
Taxes	138	162	145	169	200	174	217	180	217	177	241	177
Net Income	$ 150	$ 176	$ 158	$ 184	$ 217	$ 190	$ 235	$ 194	$ 235	$ 192	$ 262	$ 192

DSW 552574

STLCOPCB4090991

FINANCIAL SUMMARY - Expense to conduct feeding studies will be charged against 1967 and 1968 sales. No increase in sales will result in 1967 and 1968 since FDA acceptance will not be given until 1969. A loss in net income in 1967 and 1968 with no increase in sales for FDA applications will be $52,000.

In 1969 sales will begin reflecting increases due to the FDA applications. Net income will increase in 1969 by $27,000; in 1970 by $41,000; in 1971 by $43,000; and in 1972 by $70,000. See table below:

	Loss (000's)	Gain
1967	$26	
1968	26	
1969		$ 27
1970		41
1971		43
1972		70
Total	$52	$181

After 1972 the $100,000 expense to feed Santicizer 409 and Santicizer 411 for FDA approval will have been paid plus a $29,000 gain in net income.

DSW 552575

The increase in net income in 1970 will return 40% of the expenditure and in 1971 the total expense will have been paid.

RECOMMENDATIONS - Using the growth in sales, pounds and dollars and gross profit, it is recommended that we arrange to begin the tests immediately.

DISCUSSION - One of the fastest growing uses for vinyl film is food wrap applications, especially red meat wrap. The current market for red meat wrap is 140M lbs. of film of which vinyl has taken 35-40M lbs. in 1965 and is projected to go to 70M lbs. in 1966. This type of film is produced with dioctyl adipate, epoxy, some Santicizer 160 and some Santicizer 141. Due to the price differential between dioctyl adipate and Santicizer 160, it is anticipated that Santicizer 160 will find added use in these films.

The current dioctyl adipate, Santicizer 160, Santicizer 141 food wraps are satisfactory for red meat, however, there is a market for food vinyl that has higher and greater resistance to oil and fat extraction resistance.

Approximately three years ago it was found advisable to investigate the FDA approval of a polymeric type plasticizer. The particular markets involved are film and sheeting and extrusion (tubing) which need a more oil and grease resistant vinyl to fill a void that currently

STLCOPCB4090993

exists in the application of vinyl for food packaging. Projections for each industry are listed below and are the results of the field survey conducted in 1965.

Film and Sheeting	2.0$\overline{M}$ lbs.
Extrusion (tubing)	.1$\overline{M}$ lbs.
Plastisols (cap liners)	.2$\overline{M}$ lbs.
Total	2.3$\overline{M}$ lbs.

Of the 2.3$\overline{M}$ total, it is anticipated Santicizer 409 would represent 1.3$\overline{M}$ lbs. and Santicizer 411 the balance at 1.0$\overline{M}$ lbs.

Projected increases by product beginning in 1969 through 1972 are:

	S-409	S-411	Total
		($\overline{M}$ lbs.)	
1969	.5	.2	.7
1970	.9	.5	1.4
1971	1.2	.9	2.1
1972	1.3	1.0	2.3

All research work has been completed and the only information still required is the two year feeding tests. A ninety day feeding study was made but, because of the inconclusive results, the FDA has requested two year tests.

According to all concerned, the chances of success in the two year feeding study are 98% sure. Both Santicizer 409 and 411 are adipic acid polyesters and all raw materials have FDA approval. Because of the breakdown of the plasticizer in the animal during the ninety day study, FDA

STLCOPCB4090994

requires the longer feeding test. If the products fail before the two year tests are completed, our agreement with the laboratory is cancelled and no further expenditure is necessary.

Competition does exist on Santicizer 409 but no one has a product like Santicizer 411 with the same price structure. Rohm & Haas with Paraplex G-54 could "ride-in" on our Santicizer 409 approval after a short period of time after our approval has been granted. With close cooperation with the FDA, it may be possible to get an approval strictly on the composition of our products which would eliminate Rohm & Haas products. This is unlikely, so it will be planned that Rohm & Haas will get approval which will demand that once approval is granted, sales presentations must be made quickly to obtain the maximum amount of business possible.

As an example of the importance of FDA approvals, Santicizer 160 was approved about two years ago and, even though there has been restrictions because of odor primarily, sales have increased 620,000 lbs. (at 18.5¢) for an increase of $114,885 and an increase in gross profit of $52,785.

The FDA has held our petition for some time waiting a decision from us on the continuation of the program. We would like to advise FDA that we are beginning the feeding tests immediately.

DSW 552578

STLCOPCB4090995