Monsanto Company
Organic Development Department
St. Louis, Missouri

October 11, 1966

My S409 FDA file

cc: RBILG - R. E. Bilger
LCOHN - L. A. Cohn
2nd St. - M. W. Farrar
SHEIN - S. A. Heininger
RKELL - R. E. Kelly
DMARR - D. E. Marriner
HMINC - H. L. Minckler
WWAYC - W. F. Waychoff
~~EWILD - E. G. Wilde~~
df: Plasticizers, Toxicity, S-409

DEVELOPMENT DEPARTMENT CALL REPORT NO. 4701

U. S . Stoneware, Div.
Chamberlain Engineering
Stowe, Ohio

Date of Call: Late September, 1966 (by telephone)

For U.S. Stoneware: Mr. B. M. Saffian, Res. & Dev.

For Monsanto: R. M. Parks

Purpose of Call: Bernie Saffian called to discuss the status of our attempts to obtain FDA acceptance for Santicizer 409, to plead for frequent status reporting, and to define the status of and plans for their new product program plus the results of their new-market studies.

Summary of Results:

1. The application for the Santicizer 409-plasticized Tygon tubing is on-the-farm milk handling tubing (milking machine and cream separator) which now uses a rubber tube.

2. The total U.S. market for this tubing equates to 8 million pounds of polymeric plasticizer per year. Because of the jump on their competition, Stoneware feels that they could hold on to a 50% market share. Therefore, their purchases of Santicizer 409 would grow to 4 million pounds during 1971.

3. Stoneware has completed all of their in-house testing of the Santicizer 409 vinyl tubing and plans to initiate field studies in early 1967, with initial commercial shipments to be made late that year.

DSW 552579

STLCOPCB4090996

4. If we were to initiate feeding studies on Santicizer 409 by late 1966, their developmental plans would dovetail our feeding study plans.

5. The status of our Santicizer 409 feeding study program was defined, i.e., hoped-for initiation of studies by or at year-end, review of study results at 6-months and 1-year intervals, etc.

6. Since the 4 million pounds of sales of Santicizer 409 to U. S. Stoneware is above our earlier estimates, the Table which defined new potential sales of an approved Santicizer 409 (developed by Marketing) has been updated to include this new data. The revised potential is in the Details section.

Action: Development

1. Obtain written approval from Management to initiate the feeding study program yet in 1966.

2. Following written approval and during discussion with the selected testing agency, establish a feeding study protocol.

3. Obtain approval for the protocol from FDA via a joint meeting with a representative of the testing agency at FDA.

4. Initiate feeding studies before the end of 1966.

Details:

Bernie Saffian had talked earlier with Mr. Darby in an attempt to obtain status information on the FDA acceptance of Santicizer 409. Mr. Darby referred him to the writer to detailed status and plans.

After stating that we are attempting to initiate studies before year-end, Bernie said that he would like to review the U.S. Stoneware program, their plans for the future and the results of the market study that their marketing department had just completed.

STLCOPCB4090997

U. S. Stoneware has determined that the total U. S. market for Santicizer 409-plasticized Tygon tubing equates to 8 million pounds of plasticizer and that Stoneware (because they expect to be first in this market with a product) can achieve and retain a 50% share of the market. Their share will equate to 4 million pounds of Santicizer 409.

Stoneware has completed all of their in-house testing of their tubing and are now initiating limited field studies. Therefore, our timing (i.e., by the end of 1966) for initiating feeding studies dovetails theirs. The tubing will be sold to the dairy farmer and used as a replacement for rubber tubing on milking machines.

* *

Earlier, Marketing had evaluated the markets for Santicizer 409 with and without FDA acceptance. From their figures, it appeared that feeding studies, because of new potential profits, could be justified. However, the expected sales to Stoneware were below the figures now presented by them. Table I presents an updating of new expected sales for Santicizer 409 with and without FDA acceptance and includes the new Stoneware numbers. Table II compares the new "with" to the old "with" numbers where earlier the payout time for the costs of FDA acceptance had been reduced from less than 3 years to less than 2 years. Most important, however, is the new profits which will accrue to Santicizer 409 in the 3rd to 5th year after FDA acceptance (increasing from a total of $0.35 million to $1.35 million)!.

/ph/sn R. M. Parks

Attachments, Tables I and II

DSW 552581

STLCOPCB4090998

TABLE I

Expected Sales of Santicizer 409 With and Without FDA Acceptance

	Without		With		Increase	
	Lbs.	$ GP	Lbs.	$ GP	Lbs.	$ GP
1968	3.2	0.37	3.3	0.38	0.1	0.01
1969	3.4	0.37	5.3	0.58	1.9	0.19
1970	3.5	0.39	6.7	0.74	3.2	0.35
1971	3.6	0.38	8.2	0.86	4.6	0.48
1972	3.8	0.38	9.0	0.90	5.2	0.52

(in millions of units)

TABLE II

Expected New Sales of Santicizer 409 with FDA Acceptance

	Old Figures		New Figures		Increase	
	Lbs.	$ GP	Lbs.	$ GP	Lbs.	$ GP
1968	3.2	0.37	3.3	0.38	0.1	0.9
1969	3.9	0.44	5.3	0.58	1.4	0.14
1970	4.3	0.47	6.7	0.74	2.4	0.27
1971	4.8	0.50	8.2	0.86	3.4	0.36
1972	5.1	0.53	9.0	0.90	3.9	0.37

DSW 552582