1997

The Justification of a packaging line based on capacity issues

Chin Ho

THE JUSTIFICATION OF A PACKAGING LINE BASED ON CAPACITY ISSUES

By

Chin Siong Ho

A Thesis

Submitted to the

Department of Packaging Science

College of Applied Science and Technology

in partial fulfillment of the requirements

for the degree of

MASTER OF SCIENCE

Rochester Institute of Technology

1997

Department of Packaging Science
College of Applied Science and Technology
Rochester Institute of Technology
Rochester, New York

Certificate of Approval

M.S. DEGREE THESIS

The M.S. Degree thesis of Chin Siong Ho
has been examined and approved
by the thesis committee as satisfactory
for the thesis requirements for the
Master of Science Degree

[Names Illegible]

JULY 1997

Date

Thesis Release Permission

ROCHESTER INSISTUTE OF TECHNOLOGY

COLLEGE OF APPLIED SCIENCE AND TECHNOLOGY

Title of Thesis: THE JUSTIFICATION OF A PACKAGING LINE BASED ON CAPACITY ISSUES

I, Chin Siong Ho, hereby deny permission to the Wallance Memorial Library of the Rochester Institute of Technology to reproduce my thesis, in whole or in part.

JULY 1997

Date

ACKNOWLEDGEMENTS

I wish to acknowledge several people, without whom this study and thesis would have not been suceessful. I am especially grateful to John Williams, who has as much to do with this project as I have. His experience, knowledge and patience (who would have known) has allowed this study to make some sense and fun. To all the good times ahead!

I am also especially thankful to Fernando Garcia, who has left us for better prospect with DuPont. Fernando, your wisdom and advice have hopefully been put to good use.

DEDICATION

This thesis is dedicated to the most important person in my life; my wife, Lilian. Besides being the 'editor' of the text, her encouragement and patience was the most motivating factor to finishing the thesis.

The Justification of a Packaging Line Based on Capacity Issues

By

Chin Siong Ho
1997

ABSTRACT

Due to the phenomenal increase in the long range marketing forecast for the products manufactured at the Garden City site of DuPont Merck Pharmaceuticals, a capacity problem was identified. This paper evaluates the impact of the increased forecast and demands on the packaging operations, and also the justification of a packaging line to support the expected capacity overload. It addresses different alternatives available to the company to support the demand and evaluate these options based on cash flow analysis. In addition, the study allows the general reader outside the company to understand the methodology involved in the justification of a packaging line and the tools to evaluate such a project. Based on the excellent financial results of meeting the product demand internally versus outsourcing this demand to a contract packager, this study recommends that management approve the funding for the project.

TABLE OF CONTENTS

Appendixes

INTRODUCTION

The DuPont Merck Pharmaceutical Company, with headquarters in Wilmington, Delaware, is a global manufacturer of oral solids and parental ethical drug products. Manufacturing facilities for oral dosage and parental drugs are located in Garden City, New York and Manati, Puerto Rico. The company also has a Radiopharmaceutical division.

A new drug used for the treatment of Acquired Immune Deficiency Syndrome (AIDs) is currently in the pipeline of the company. Filing of the New Drug Application (NDA) with the Food & Drug Administration (FDA) is expected by January 1998 and approval by the agency is anticipated in the second quarter of 1998. Marketing and Sales have provided a phenomenal forecast for the product and expectations of the company are extremely high. Due to maximized capacity in the Manati, P.R. site, management has made the decision to manufacture and package the product in Garden City, New York.

The New York site is currently supporting all production of ENDO Laboratories L.L.C., the generic subsidiary of DuPont Merck Pharmaceuticals, and two major Merck products -- Hyzaar and Cozaar -- drugs for the treatment of hypertension and high-blood pressure. The site currently operates with two shifts for the packaging operation. With the current operational mode of five packaging lines (two trade tablet/capsule bottling line, one sample tablet line, one liquid bottling line and a Hospital Unit Dose (HUD) or blister packaging line), the site is operating at close to 75% capacity for the packaging operation. In addition, space for manufacturing, packaging, warehousing, and offices, etc., is a

premium on the site. The local county zoning law will not permit further site expansion, hence any renovation or facility modifications to increase manufacturing/packaging capacity will have to be within the current area.

With the anticipated launch of the AIDs drug in 1998 combined with the huge demand and forecast for Hyzaar and Cozaar, the Garden City site faces a packaging capacity and expansion issue which requires immediate attention.

This paper will study the impact on the site with the expected increase in manufacturing and packaging production. It will address the issues of anticipated maximization of the packaging capacity, investigate alternatives to provide for both immediate and long range solution to the problem, and discuss options related to expansion of the site for increase manufacturing and packaging activities.

CHAPTER 1 - ASSUMPTIONS

Due to the nature of the study, assumptions have to be made along with results gathered from other studies to support this paper. The following is a list of assumptions:

1) There are 400 operating minutes per shift.

2) Lines 2 and 3 have a net rate of 50 bottles per minute (BPM) and require a total of seven operators and mechanics for each line to operate and maintain the machinery.

3) Line 2 is dedicated to one bottle size. However, Line 2 will still require line cleaning and changeovers for different product strengths. In addition, the reliability of the equipment on the line, due to an average age of sixteen years, is questionable. Based on actual studies completed over a four-week period, the line is only operating at 60% efficiency on the first and second shifts.

4) Line 3 is not dedicated to a bottle size or product. Changeovers are much more frequent, resulting in more downtime and lower efficiency. Based on actual studies completed over a four week period, the line is only operating at 40% efficiency on the first and second shifts.

5) Since the site does not currently operate with a third shift, the efficiency of a third shift on the lines has been estimated to be 66% of the actual efficiency on the first and second shifts due to lack of support from other departments (e.g., warehousing, QA, labeling operations, etc.), more frequent equipment breakdowns in a three shifts environment, etc.

6) It is assumed that there are 200 shifts/year with a one shift/5 days operating environment, or a maximum of 600 shifts/year in a three shifts/5 days operating environment. This include holidays, weekends, plant shutdowns, days for training, etc.

7) The site will operate in a three shifts/5 days environment. All calculations of capacity will carry this assumption.

8) A yearly 4% inflation rate is used for all calculations.

9) Packaging Labor rate is taken as $18/hr with benefits, with 8 hr./shift.

10) All alternatives investigated assumes that manufacturing can meet the demands required to the year 2005. Manufacturing (granulation, compression, coating departments) will have to supply the final dosage forms of the product.

CHAPTER 2 - CURRENT SITUATIONS

Cozaar and Hyzaar trade packages are currently packaged on packaging Line 2 with Line 3 serving as a back-up. The two products currently have a total of four different strengths, packaged in HDPE bottles of 30, 90 and 100 counts. The two products were launched in 1995 with an original forecast that has increased dramatically, mainly due to the availability of the Active Drug Substance (ADS), from the most recent forecast provided by the customer. In addition to the unexpected huge increase in demand for Cozaar and Hyzaar by the customers, marketing has also recently released its expected sales forecast for the AIDs drug. Together, the three drugs have a total demand forecast (in millions of bottles) shown in Table 1.

Table 1

Year	1997	1998	1999	2000	2001	2002	2003	2004	2005
Demand	6.17	9.50	12.60	18.80	22.0	24.0	27.0	28.0	29.0

CURRENT CAPACITY CALCULATIONS

Based on the assumptions made in Chapter 1, the following is the capacity calculation for each current packaging line:

CURRENT LINE 2 CAPACITY:

1st and 2nd shifts:	50 BPM x 400 min./shift x 2 shifts x 60% = 24,000 bottles
3rd shift:	50 BPM x 400 min./shift x 1 shift x 40% = 8,000 bottles

CURRENT LINE 3 CAPACITY:

1st and 2nd shifts:	50 BPM x 400 min./shift x 2 shifts x 40% = 16,000 bottles
3rd shift:	50 BPM x 400 min./shift x 1 shift x 30% = 6,000 bottles

From the above calculation, it is determined that Lines 2 and 3 combined will have a production capacity of 54,000 bottles per day in a three-shift environment. Hence, with the assumption that there are 200 actual working days in the Garden City site, the total maximum capacity for Lines 2 and 3 is 10.8 million bottles/year.

COMPARISON OF CURRENT DEMAND AND CAPACITY

Since the total production capacity of Lines 2 and 3 is 54,000 bottles per day, the number of days that will be required by the packaging operations to meet the demands, as listed on Table 1, can be calculated by dividing demands of the respective year over the total daily capacity of the lines. With this information, the number of shifts that will be required to meet the total demands can also be calculated. Table 2 shows the above calculation and summarizes the results for 600 shifts:

Table 2

Year	1997	1998	1999	2000	2001	2002	2003	2004	2005
Demand	6.17	9.50	12.60	18.80	22.0	24.0	27.0	28.0	29.0
Capacity	10.8	10.8	10.8	10.8	10.8	10.8	10.8	10.8	10.8
Days	114	176	233	348	407	444	500	519	537
Shifts	343	528	600	600	600	600	600	600	600

Given the above details and results, it has been shown that the packaging capacity of Garden City will be maximized in 1999. The following sections will address possible solutions with respective pros and cons.

CHAPTER 3 - IMMEDIATE IMPROVEMENT OPPORTUNITIES

In any operations management text, the four basic principles of manufacturing are the four M's - Methods, Materials, Machinery and Manpower. A successful justification of a manufacturing related project has to include these principles. The idea of 'immediate improvement opportunities' relates to improvements in current processes and also the four M's.

In a packaging or manufacturing operation, the first step to increasing production capacity is to study the current methods of production and implement improvements to current operations. These improvements could be as simple as providing proper training to packaging operators and/or mechanics to increase the speed of individual equipment, or simply "tweaking" the machines to optimum operation levels. Other effective fixes may be:

- Improving packaging components that are supplied to the equipment. For example, in the cartoning process, the dimensional tolerances of the cartons are extremely important to the efficiency of the cartoner. In addition to the dimensions, the types of paperboard used or the storage conditions of the cartons may also affect the behavior of the cartoner. Warping of cartons due to improper storage conditions is a common factor resulting in lower equipment efficiency. All packaging components -- bottles, caps, labels, cartons, inserts/outserts, shippers, and films -- have an effect on the speed of the packaging line.

- Improving existing methods of production such as the packaging operations, the morale of the operators, the delivery of components to the packaging line, the ergonomics of the equipment and their effect on the operators, downtime of the equipment due to the prior manufacturing step (i.e., is the product ready to be packaged?), proper scheduling and planning, and the maintenance program of the packaging equipment can help in improving efficiency of the production/packaging site.
- The use of a third shift if it has not been considered. Going to a three shift operation in any manufacturing operation is always an ideal solution to a short term problem. However, the long term effects of three shift operations must be studied carefully if it is not a common practice by the company. As time progresses in a three-shift environment, production efficiency will tend to be affected as problems with equipment reliability (breakdown) become more prevalent. In addition, if the third shift is not staffed appropriately to meet the packaging and/or manufacturing operations, then downtime increases. For example, if there are less warehouse staff during the third shift and components unexpectedly run out before the end of the shift, then the packaging line efficiency will be affected due to lack of components.
- Improving and/or changing existing line equipment. This option will provide slight improvements that may be required on the packaging

lines to increase capacity and efficiency. Normally, improvements are made to the 'bottleneck' equipment on the line (the limiting or slowest equipment of the line), thereby increasing the net output of the line.

In the current case, all of the above immediate improvement opportunities have been investigated, and some have been implemented already. Packaging components have improved with the use of better alternate suppliers, and in some cases by working with the vendors on the problems to improve the components. In recent months, re-training on most of the equipment in the packaging area was provided to all mechanics.

Beginning in August 1997, Line 3 will undergo a major refurbishing project in the front end of the packaging line. This project involves the installation of a new bottle cleaner/unscrambler, a refurbished filler, new conveyors and controls for the line. The expected outcome of this installation is increased efficiency of the line by a net output of 30 BPM to 50 BPM. The expected completion date of this project is October 1997, hence providing for the required capacity as forecasted for 1998. Although short-term improvements were investigated for Line 2, the feasibility for improving the line was not deemed to be appropriate for several reasons:

- Line 2 is a dedicated line used in the packaging of all Cozaar and Hyzaar (a major factor in the increase in demand forecast). There is essentially no opportunity to bring the line down for any installation work of new equipment for a lengthy period.

- The average age of the equipment on this line is approximately sixteen years. Except for the bundler which was installed in 1993, all of the equipment will need to be replaced. For this reason the reliability of Line 2 is questionable and the need for a new line at the site should be properly investigated.
- The 'rebuilding' of Line 2 is estimated to cost approximately $1.8 million. However, this investment will not provide for the capacity that is required to meet the expected demands due to speed limitation that the line will face as a result of limited floor space for equipment in the current area. A previous investigation by the Packaging Engineering group on the improvements of Line 2 showed an increase in net output of the line from 50 BPM to 80 BPM. The increase in line output by 30 BPM is still insufficient to meet the demands forecasted.

Having previously studied the opportunities for improvements to increase the current capacity of the lines thoroughly, this study will address the remaining options of Contract Packager and a New High Speed Line Installation, appropriately called Line 6.

CHAPTER 4 - OTHER ALTERNATIVES

CONTRACT PACKAGER

Contract packagers provide one of the most unique services to the packaging industry. Of the approximately 330 contract packaging companies in the United States, less than 10% are pharmaceutical contract packagers.[1] The general concept of a contract packager is to provide the additional capacity a manufacturer would otherwise be required to invest, including labor, equipment, material, training and documentation. Although pharmaceutical contract packagers and regular contract packagers provide the same type of service to the packaging industry, pharmaceutical contract packagers are considered by the FDA as pharmaceutical packaging companies. Therefore, the same regulations which apply to a pharmaceutical company will also apply to a contract packager, including rules governed by the Current Good Manufacturing Practices (cGMP).

A pharmaceutical company may approach the use of a contract packager for some of the following purposes:

- Research & Development (R&D) packaging and Clinical Packaging for Clinical Studies during the development of a new drug.
- Rework or repackaging of a previous batch due to quality or manufacturing reasons. For example, if the labeling of a product that was already packaged by the company has to be changed due to regulatory reasons, most companies will send the whole batch to a contract packager to be reworked. The operation will include

[1] Jenkins & Osborn, Packaging Drugs and Pharmaceuticals, Technomic Publishing Company, Inc., 1993, p.14.

removing the product from the package and repackaging the product into a new package with the new required labeling information.

- Seasonal products such as cold and cough season products or allergy products which are in high demand during certain periods in the year. Hence, a company that faces changes in demands due to the season may decide to use contract packagers instead of building additional capacity to meet these cyclically-inflated demands.
- Development packaging or testing of new packaging materials for the products to be placed in stability studies to determine the effects of the materials on the drug.
- Providing the additional capacity to meet any increase in demand. Similar to the same problems faced by the Garden City site, most pharmaceutical companies have begun to use contract packagers to avoid initial investment of in-house labor and equipment to meet the increasing demands for their products. Normally, these are the smaller pharmaceutical, generic, or nutritional companies that may not have the initial capital expenditure to permit huge equipment and/or facility investments. Larger pharmaceutical companies may also require the use of contract packager for the same reasons. Although contract packagers are usually recommended for temporary increases in demand, this may no longer be true due to the competitive nature of the generic pharmaceutical business.

DIRECT LABOR COST CALCULATIONS

Continuing with the capacity calculations of the Garden City site, the cost of in-house labor (direct labor relating only to packaging) versus the cost of contract packaging must be considered. Using Table 2 as the guide, the cost of direct packaging labor in-house to meet the demands can be calculated by multiplying the cost of labor per shift by the total number of shifts to meet that particular demand for the year.

For example, using the current Line 2 and 3 capacity calculation for 1997:

Cost of Labor per shift = \$18/hr x 8 hr./day x 14 operators

= \$2016/shift

Since 1997 would require 343 shifts to meet the demand of 6.17 million bottles, the cost of labor to meet demand is then calculated to be approximately \$691,000. However labor costs will have to be adjusted for yearly inflation rate that we assume to be 4% for the following years. Also, the maximum number of shifts per year is assumed to be 600 shifts, hence no extra direct labor can be incurred beyond the 600th shift. Table 3 reflects the calculations of direct labor in the current capacity situation up to year 2000 (Refer to Appendix A for complete chart of calculations through year 2005):

Table 3

Year	1997	1998	1999	2000
Demand (thousands of bottles)	6170	9500	1260	1880
Capacity (thousands of bottles)	1080	1080	1080	1080
Days	114	176	233	348
Shifts	343	528	600	600
Cost of Labor/shift	$2016	$2097	$2181	$2268
Cost of Labor to meet demand	$691,040	$1,106,560	$1,308303	$1,360,635
Total btls to be contracted (thousands of bottles)	-4630	-1300	1800	8000
Contracted - Price/1000 btls	$298	$310	$322	$335

CONTRACT PACKAGING COST CALCULATIONS

Contract packagers that have complied with DuPont Merck's Quality Assurance Auditing Program and have been approved by Quality Assurance include PACO Contract Services in New Jersey and Packaging Coordinators Incorporated (PCI) in Pennsylvania. Quotes were requested from both companies to provide contract packaging services for bottles of 100 count, 75 cc HDPE bottle with 33 mm child-resistant closure. The finished product shall resemble the current Cozaar and Hyzaar finished products packaged at DuPont Merck (Refer to Appendix B and C for the Bills of Material for Cozaar and Hyzaar trade packaging).

The quote for PCI was more favorable than PACO's at $298 per 1000 bottles. This will be the cost to package the product into the exact packaging configuration as

described in the BOM. The cost does not include all packaging components as they will be supplied by DuPont Merck. Hence, the cost provided by PCI is their cost of labor to produce 1000 bottles. Referring to Table 3, the total number of bottles to be contracted is gathered by the subtraction of the total demand against the total current capacity of Lines 2 and 3 which is 10.8 million bottles. Hence, in 1997, a negative value is obtained since the capacity is capable of exceeding the demand, whereas in 1999, contract packaging of 1.8 million bottles will be required. Note that the increase in the price of contract services is adjusted by a yearly 4% inflation rate.

Given the above description, the yearly total cost for contract packaging can be calculated given the current capacity situation of Lines 2 and 3 as shown in Table 4 (Refer to Appendix A for complete chart of calculations through year 2005):

Table 4

Year	1997	1998	1999	2000
Demand (thousands of bottles)	6170	9500	1260	1880
Capacity (thousands of bottles)	1080	1080	1080	1080
Days	114	176	233	348
Shifts	343	528	600	600
Cost of Labor/shift	$2016	$2097	$2181	$2268
Cost of Labor to meet demand	$691,040	$1,106,560	$1,308303	$1,360,635
Total btls to be contracted (thousands of bottles)	-4630	-1300	1800	8000
Contracted Price/1000 btls	$298	$310	$322	$335
Total Cost - Contracted	$0	$0	$580,170	$2,681,676

From the results shown above, the use of contract packaging to meet the demands for that respective year will incur a yearly cost to the Garden City site from 1999 onwards. With the increase in demand, productivity in the manufacturing facility must be raised to meet the demand, or the operating costs of the company will increase.

INCREMENTAL OPERATING COST

Operating cost of a manufacturing facility includes the amount of indirect labor required to meet the demands (i.e., fixed head-count), and the operating expense of the site. Operating expenses are expenses that a company incurs in order to do business and they include such things as office supplies, safety glasses, protective gear for the operators, maintenance of equipment, etc. Another operating cost that has to be investigated for this study is the utility cost that is required to provide for the extra third shift that the site will require since the calculations for the capacity studies are based on a three-shift working environment.

The operating cost of both contract packaging and in-house packaging will increase as a result of an increase in product demand. For example, as demand increases every year, the site will have to hire more direct labor to support the increased activities. More purchasing personnel may be required to purchase the related increase in manufacturing and packaging components, or to work on the contracts with the contract packagers. More planners or schedulers may also be required as a result of the increase in activities, and more quality assurance personnel will be needed to complete the auditing of documentation related to each batch that were manufactured or packaged. These related

costs and expenses to the company have to be calculated because they will have an impact on the decision between the cost of contract packager and packaging in-house.

Several additional assumptions were made to calculate Incremental Operating Costs (IOC). They are:

- The average fixed labor cost is $60,000 with benefits included.
- The operating expenses include expenses incurred by Packaging, Warehousing and Building Services. The budget for 1998 has been decided and is assumed to have no impact on the total operating cost.
- Current utility cost on the site is based on twenty hours of usage. Inclusion of a third shift will only result in a $20,000 per year increase to utilities.[2] An inflation rate of 4% was used to calculate the anticipated increase in utilities.

With the above assumptions, all related increases in the Incremental Operating Cost for the current capacity situation are shown in Appendix D. Appendix D also represents all incremental costs for other proposals . Referring to the chart, it can be seen that two fixed headcount will be required to be added at the site in 1998 and another two will be required every two years. The increase in headcount is only for activities related to packaging (i.e., additional team leader for packaging, additional packaging operators, quality personnel in packaging, warehousing personnel to support packaging, etc.). Other departmental needs on the site for headcount increases are not considered in this study.

In the current capacity situation, the increase in operating expense becomes significant starting from the year 1999 because the packaging capacity of the site allows it

[2] Personal Communications, Director of Facility and Engineering, DuPont Merck Pharmaceuticals, Lenny Lustrino, May' 97.

to support the additional demand for a portion of that year before contract packaging is required. In the following years, the increase in operating expense is insignificant because the site capacity is at its maximum, hence, there is no need for additional operating cost to meet those demand as they will be absorbed by the contract packager and be included in the Contract price per 1000 bottles.

From the calculations shown in Appendix D, the incremental operating cost is added to the table as shown below in Table 5 (Refer to Appendix A for complete chart of calculations through year 2005):

Table 5

Year	1997	1998	1999	2000
Demand (thousands of bottles)	6170	9500	1260	1880
Capacity (thousands of bottles)	1080	1080	1080	1080
Days	114	176	233	348
Shifts	343	528	600	600
Cost of Labor/shift	$2016	$2097	$2181	$2268
Cost of Labor to meet demand	$691,040	$1,106,560	$1,308303	$1,360,635
Total btls to be contracted (thousands of bottles)	-4630	-1300	1800	8000
Contracted - Price/1000 btls	$298	$310	$322	$335
Total Cost - Contracted	$0	$0	$580,170	$2,681,676
Incremental Operating Cost(IOC)	$0	$140,000	$290,800	$357,632

Given the table above, all significant cost has been considered to meet the forecasted demands. There are other costs involved that were excluded such as the cost

of shipping bulk tablet/capsule drums to the contract packager . Although these costs will add to the unit cost per bottle, only the major cost factors are included in this study. For example, the number of tablets in a drum may vary for the AIDs drug since studies have not been completed for the storage and handling of bulk tablets. Therefore, it would be helpful to keep in mind that the unit cost per bottle will most likely be higher when contract packagers are used to fulfill the demands.

LABOR COST PER UNIT BOTTLE CALCULATIONS

From the above calculations, the labor cost per unit bottle can be obtained to allow the evaluation and comparison of the cost between contract packagers and other alternatives. Since the study assumes that all activities prior to packaging (i.e., manufacturing) have been accounted for and are capable of meeting the demands; and that all packaging component costs will still be required regardless of the alternatives chosen, the most logical comparison that can be made between each alternative, is the use of labor cost per unit bottle.

The total cost to meet the demand each year comprises of the cost of labor to meet the demand for each year (i.e., the direct packaging labor), the total cost for contract packaging each year, and the incremental operating cost (IOC) that is incurred every year. This is the total cost to the site to meet the demand for the respective years. Hence, the division of the total cost by the demand for that year will result in the labor cost per unit bottle.

$$\text{Cost/unit bottle} = \frac{\text{Total Cost Labor + Total Contract Cost + IOC}}{\text{Demand}}$$

Table 6 below shows the total cost per unit bottle (Refer to Appendix A for complete chart of calculations through to year 2005):

Table 6

Year	1997	1998	1999	2000
Demand (thousands of bottles)	6170	9500	1260	1880
Capacity (thousands of bottles)	1080	1080	1080	1080
Days	114	176	233	348
Shifts	343	528	600	600
Cost of Labor/shift	$2016	$2097	$2181	$2268
Cost of Labor to meet demand	$691,040	$1,106,560	$1,308303	$1,360,635
Total btls to be contracted (thousands of bottles)	-4630	-1300	1800	8000
Contracted - Price/1000 btls	$298	$310	$322	$335
Total Cost - Contracted	$0	$0	$580,170	$2,681,676
Incremental Operating Cost(IOC)	$0	$140,000	$290,800	$357,632
Total Labor/Contract/IOC Cost	$691,040	$1,246,560	$2,179,274	$4,399,943
Total Cost per Bottle ($)	0.112	0.131	0.173	0.234

CHAPTER 5 - PACKAGING LINE INVESTMENTS

The investment of a packaging line is a critical decision that has to be studied thoroughly by a project/packaging engineer. It is important that the person overseeing such a project be given strong support from management, production, maintenance, and vendors.[3]

Unlike buying a single piece of equipment, a packaging line include several pieces of equipment that must work effectively together as a system; communicating and controlling the speed of each other to provide the most efficient way of completing the process. There are several factors and decisions that have to be made prior to scoping out the cost of the packaging line:

- Net production rate or speed must be calculated based on the expected efficiency of the line so that the capacity calculations can be determined.
- The finished product must be presented. Very often, the final configuration of the product will determine the success of the project or line installation. Marketing involvement must be constant and any changes to the design of the final package must be communicated immediately. Any change or delays in developing the final package design will result in delaying the project and increasing project cost.
- A functional description of the process involving the lines must be written so that all parties involved can work with the same document. This document is

[3] W. Soroka, Fundamentals of Packaging Technology, IOPP, Hendon, Virginia, 1995, p. 445.

important because it allows multiple vendors to bid for the same equipment. Unlike the engineering specification (which is a much more descriptive document), this document allows the vendors to provide a good quotation for the equipment that the project engineer will be investigating.

- Another important factor, especially in the case of Garden City, is space. Where do you install this packaging line? In most pharmaceutical companies, space is a limiting factor in the packaging area. Hence, the line must be constructed with the space issue constantly in mind.

CALCULATIONS OF PACKAGING LINE SPEED AND CAPACITY

The most critical machine on the packaging line is usually the slowest equipment. In the pharmaceutical packaging industry, the tablet/capsule filler is generally the limiting factor or equipment on the line. In the industry, the fastest filling equipment is a Slat Filler that is made by several manufacturers such as DT Lakso and Merrill-Stokes. The maximum design speed of a Slat Filler is approximately 400 BPM based on a 100 count fill with 20 bottles per drop.[4]

From the filler, the process of the packaging line will include a Capper, Induction Sealer, Retorquer, Labeler, Outserter and a Bundler. Hence, given an average efficiency of 85.8% on each individual equipment, the net output speed of the line can be calculated by.[5]

---

[4] Personal Communications, Technical Services Manager, DT Lakso, Bill Lawton, Nov.' 96..

[5] Zeph, P., Hoe to Analyze Packaging Line Performance. IOPP, Herndon, Virginia, 1993.

Net Output Speed = 400 BPM x $(0.858)^6$

= 160 BPM.

From the formulas and assumptions obtained from the current capacity calculations in the previous section, a net output speed of 160 BPM will give the following capacity:

1st and 2nd shifts:	160 BPM x 400 min./shift x 2 shifts x 60% = 76,800 bottles
3rd shift:	160 BPM x 400 min./shift x 1 shift x 40% = 25,600 bottles

From the above, if the line is designed with a net output of 160 BPM, it will have a daily capacity of 102,400 bottles in a three-shift working environment. Hence, with the assumption that there are 200 actual working days in the Garden City site, the total maximum capacity for this line is approximately 20.5 million bottles/year.

Using the methods obtained from the previous sections for calculating the cost of direct labor to meet demand (Proposal A will require ten operators to run the line, refer to chapter 7), the cost for contract packaging services and the incremental operating cost, a chart similar to Appendix A is obtained (Refer to Appendix E). This scenario or alternative will be known as PROPOSAL A.

PROPOSAL A ALTERNATIVE

The major difference between the calculations for Proposal A and the Current Capacity besides the huge increase in capacity, is the Incremental Operating Cost. Since Proposal A allows the site to continually meet the demand to package up to 20.5 million

bottles before seeking contract packaging assistance, the operating cost of the site will have to reflect the increase in the expected productivity.

Referring to the chart in Appendix E, PROPOSAL A, the packaging line with one filler, will allow the Garden City site to meet demands until the year 2000 and the need for contract packaging will occur only beyond 2001. Although Proposal A provides for a good solution, other alternatives that cater to the demand should be investigated

PROPOSAL B - ALTERNATIVE

In Chapter 3, Immediate Improvement Opportunities, the investment and project on Line 3 to provide for the additional net speed and capacity of the line to meet the demand for 1998 was discussed. The project will involve the replacement of a current filler to a newer and faster filler. The old filler (which is also a slat filler but much older and less sophisticated) will be written off after the completion of Line 3 Project. However, if the filler could be rebuilt to provide for the extra capacity, a minimum of $300,000 could be saved in the cost of a new filler.

This opportunity prompted an immediate investigation. A positive outcome resulted after much work with several vendors including DT Lakso,[6] Universal Machines,[7] and Automated Packaging Systems[8] All of the vendors believed that the old filler could be rebuilt to provide better controls and newer electrical technology; and improvements to the machine would result in better compliance with Good Manufacturing Practices (GMP)

---

6 Personal Communications, Vice-President, Operations, DT Lakso, Jim Hills, Jan. '97.

7 Personal Communications, Sales & Technical Manager, Universal Machines, Dave Burdan, Feb'97

8 Personal Communications, President, Automated Packaging Systems, Tom Stange, Dec.' 96

regulations. The rebuilt machine will also be capable of providing a maximum design speed of 200 BPM.

With a filler that could provide for a maximum design speed of 200 BPM, the net output rate could then be determined as:

$$\text{Net Output Speed} = 200 \text{ BPM} \times (0.858)^6$$

$$= 80 \text{ BPM}.$$

Proposal B is the combination of both fillers, the new high-speed filler with a maximum design speed of 400 BPM and the rebuilt filler with a maximum design speed of 200 BPM. Together, both fillers will be able to produce a net output of 240 BPM. In addition, having a second filler with a separate fillroom on a packaging line will improve the operating efficiency since one fillroom could be cleaned and changeover while the other finishes the run for that particular product. Furthermore, the efficiency of the machine will improve greatly from the older machines on Line 2 and 3. Hence, the operating efficiency of the line on Proposal B will be greater than the 60% used for the first and second shifts and the 40% for the third shift.

This study assumes that two separate fillrooms on the line will provide a minimum improvement of 10% to 70% operating efficiency. Given this assumption, the capacity calculation using the same formulas as the sections above will show the following:

1st and 2nd shifts:	240 BPM x 400 min./shift x 2 shifts x 70% = 134,400 bottles
3rd shift:	240 BPM x 400 min./shift x 1 shift x 46.6% = 44,736 bottles

Again, from the above, it can be determined that if the line is designed with a net output of 240 BPM, it will have a daily capacity of 179,136 bottles in a three-shift working environment. Hence, based on the assumption that there are 200 actual working days in the Garden City site, the total maximum capacity for Proposal B is approximately 35.8 million bottles/year.

Given the maximum capacity of Proposal B and based on the methods obtained from the previous sections for calculations of the cost of direct labor to meet the demands (Proposal B will also require ten operators to run the line, refer to chapter 7), the cost for contract packaging services and the incremental operating cost, we obtain a chart shown in Appendix F, which is similar to the chart in Appendix A.

From the chart, we have shown that a capacity of 35.8 million will completely remove the needs for contract packaging to meet the additional demands. In addition, comparing Proposal B to Proposal A, the unit cost of labor decreases by approximately 50% (e.g., from $0.108/bottle to $0.059/bottle in the year 2001). There are several reasons for this decrease:

- With a greater daily capacity in Proposal B, there is no actual need of the packaging operations to go to a third shift since the maximum number of shifts to meet demand in year 2005 is 486 shifts. This means that packaging would only need another 86 shifts to meet the maximum, which would not justify a complete third shift for the year. Instead, management would be better off using 10-hour shift whenever required to meet the demands.

- The additional capacity of Proposal B also mean that the productivity per unit labor is much better because of the speed of the machines.
- Without the need of a full third shift, the total incremental operating cost (fixed labor, operating expense and utilities) will also decrease. As a result of the decrease in IOC, the total cost of the bottles decreases.

PACKAGE DESIGN AND CONFIGURATION

During the determination of packaging line speed and capacity research, one has to begin pursuing the package design and configuration of the products in question. Since both Cozaar and Hyzaar are existing products, the package configurations were already determined.

To determine the package configuration of the AIDs drug, the project engineers will have to work with both Research and Development (R&D) scientists and Marketing personnel. This is the stage where all changes have to be communicated to the project engineer and vice-versa. For example, the requirements for desiccant on the AIDs package have not been determined. Stability studies are held concurrently and results will not be known until a much later date. The project engineers will have to consider this addition to the package and the equipment that may be necessary to perform the function. Hence, the project budget will have to include these requirements.

The package configuration that is determined will not be written in stone. R&D will continue to obtain results that may require the package to change, Marketing may request for special presentation of the drug either with additional literature information to

educate patients or even the use of folding cartons. Hence, one of the methods that a project engineer can use to account for these changes is the use of proper documentation such as The Addition To The Line (ATL) Request.

The ATL request is basically a form that describes the packaging configuration of a package. Unlike a Bill of Material, which is used for current packages in production, an ATL is a request to change a new product or an existing product. This request is controlled by the Packaging Engineering Department. For instance, if marketing requests a change, an ATL will be used to convey the intended change. The request will then allow all affected departments such as Packaging Engineering, Site Engineering, R&D, Marketing, Regulatory Affairs and Quality Assurance to evaluate, review, comment and approve before the decision to change is made. Once the document is signed off, the individual departments will have the responsibility to assess the effect of the change and make the necessary changes to their operations or documentation to allow the change to be effective.

Once the ATL is formalized, the project can continue to scope out the necessary equipment to perform the function that will provide the final packaging configuration to be produced on the packaging line.

PROCESS DESCRIPTION OF PACKAGING LINE

Once the package design and configuration is determined, a process description of the packaging line has to be formulated and written. The purpose of writing the process description is to provide an internal (within the site management) consensus on the

different operations and equipment that will be required in the packaging operations to produce the final packaging configuration for distribution and sale. The description should be based on the best possible solution to the problems and have as little manual operation as possible.

In this study, Line 6 will be designed to handle 75 cc and 150 cc HDPE bottles. The primary products that it includes are all trade packages of Cozaar and Hyzaar in the 75 cc container. Line 6 will also be capable of handling the 150 cc bottles for the packaging of the AIDs product. The following is a brief process description of the line:

- A **Feed System** capable of handling bulk supply of bottles will deliver and transfer the bottles.
- The bottles will be dumped into a **Hopper** where it will be elevated into two Unscramblers for bottle cleaning and orientation.
- The bottles will then be filled with desiccant, if required, by two **Desiccant Feeders**.
- There will be two **Fillrooms** for the line. A discharge conveyor will deliver the bottles from each unscrambler to the respective fillrooms where the **Tablet/Capsule Filler** will fill the bottles to the designated count.
- Once filled, the bottles will converge to a single conveyor delivering the bottles to a **Capper**.
- A bulk supply of caps will be transferred from a **Hopper** to a sorter/orienter which will deliver the caps to the delivery chute. The

capper chucks will remove the caps from the delivery chute, place it onto the bottle and apply the cap to the required application torque.

- The filled and capped bottles will be transferred through a **Bottom Code Labeler** for Lot Number and Expiration Dating during Brightstocking of packaging runs.
- The container/closure system will then be conveyed through a **Induction Sealer** unit for caps with foil seals.
- The sealed bottles will then proceed to a **Retorquer** unit to obtain the specified removal torque for the container/ closure system.
- The bottles will then be conveyed into a **Labeler** for application of the labels and outserts onto the bottle.
- The outserts will be randomly supplied in bulk into a **Feeder** which will transport the outserts into the labeler for application onto the bottle.
- Once the bottle is filled, capped, sealed, labeled and affixed with outsert, it will be conveyed into a **Bundler** for collation of the bottles to the desired pattern and then shrink-wrapped into bundles.
- The bundles will be conveyed to a **Print and Apply Labeler** for the bundle label to be printed and applied on top of the bundle.
- The labeled bundles will be automatically placed into a **Case Erector/ Packer** where shippers will be erected to accept bundles and then sealed with pressure sensitive tape.

- The shipper is then conveyed to **a Print and Apply Labeler** for the shipper label to be printed and applied onto the corner of the shipper.
- The labeled shipper will continue to an **Ink Jet Printer** for automatic printing of the Revision Number and Sequential Shipper number.
- The finished shipper will then be conveyed into an **Automatic Palletizer** for palletization of the shippers to the required pallet pattern.
- The finished pallet will be conveyed to the **Stretch-Wrapper** to unitize the pallet for shipping of the finished product.

With the process description above (Note that all equipment relating to the process are in bold), investigation of the machinery required for the line can now begin. In addition, the process description can be used as a guide in writing the Functional Description of the line.

However, unlike Proposal A and B which are proposals derived from the calculation of speed and total capacity of the line to meet the demands without regarding the need of automation, the process description is actually another proposal that lists automation of the line as its definition. For example, based on the package design and configuration, Proposal A and B will require the automation of a packaging line to the bundler, where the bottles are collated and shrinkwrapped. From the bundler, the process description as shown above could be manual instead of automated (i.e., the bundle sticker could be applied manually by an operator, the labeled bundle could be placed manually into the manually labeled shipper, the shipper would have to be erected, taped and palletized manually, and the finished pallet could be manually stretch-wrapped).

Hence, Proposal C is the proposal that requires the least number of operators on the line since the process is fully automated. With this decrease in labor, the calculations for the cost of direct labor to meet the demands (Proposal C will require five operators to run the line), the cost of contract packaging services and the incremental operating cost have to be shown. The chart in Appendix G shows the calculations for Proposal C.

FUNCTIONAL DESCRIPTION DOCUMENT

The Functional Description (as shown in Appendix H) is a document that serves as a preliminary specification for the requirements of the line. It is used to provide prospective vendors and/or integrators the complete picture of the process and allow them to understand the requirements of the project. Although it does not remove the need for further communication with the vendors, the Functional Description provides a clear objective of the project and allows the prospective equipment vendors the opportunity to investigate the type of machine that they would recommend to meet the specified requirements. From this document, quotation of the equipment and the timeline to build the equipment should be provided by the vendors. Individual machine capabilities should also be assessed.

ASSESSMENT OF PACKAGING EQUIPMENT AND SERVICES

In Proposal B, it was determined that the combination of the two fillers in separate fillrooms will provide a maximum design speed of 600 BPM and a net line output of 240 BPM. From the design speed of the combined fillers, the minimum design speed of

the rest of the equipment on the line can be determined based on the assumption of 85.8% efficiency for each piece of equipment. The minimum design speed of the equipment downstream is actually based on the net output of the previous equipment.

Starting from the fillers at 600 BPM, the minimum design speed of each equipment downstream is shown below in Table 7:

Table 7

EQUIPMENT	DESIGN SPEED	EFFICIENCY	NET OUTPUT
FILLERS	600 BPM	85.8%	515 BPM
CAPPER	515 BPM	85.8%	442 BPM
INDUCTION SEALER	442 BPM	85.8%	379 BPM
LABELER/OUTSERTER	379 BPM	85.8%	325 BPM
BUNDLER	325 BPM	85.8%	279 BPM
CASE PACKER	279 BPM	85.8%	240 BPM

Once the individual equipment's minimum design speed is calculated, the functional description document can be used to hold preliminary discussion with prospective vendors. It is also appropriate at this time to consider the need for integration services to the project or other types of installation requirements and its related costs. Integration is basically the action of pulling all the different equipment together to perform the final objective of the packaging line (i.e., installation of the equipment into a system). For example, a project of this size will normally require some type of installation services since DuPont Merck is a pharmaceutical company and not an engineering company where

resources are limited. Hence, it is imperative to determine the installation services which is suitable and cost effective. The packaging industry has basically three choices of integration services; Turnkey, Integrakey and Integration services.

In a Turnkey situation, the whole project is completed by the vendor of choice. The company (DuPont Merck) seeking the integration services will basically leave all decisions to the vendor. The vendor will engineer the whole project by selecting all the equipment, write all the purchase and engineering (performance) specifications, provide all the purchase orders, perform all checkouts of equipment, test them and assemble the final configuration at the company's site. The company's function is to provide the cost of the project. This option should only be used when there is completely no internal resources in the company to work on the project.

In an Integrakey situation, the vendor works as a team with the company's project/packaging engineers to develop the purchase and engineering specifications for all equipment to be utilized. The company (DuPont Merck) will place the purchase orders for all the equipment and services. The vendor will participate in the checkouts along with DuPont Merck before assembling the equipment for testing at the vendor's site. After the testing is performed (usually called Factory Acceptance Test, FAT) and approved by the company, the vendor will then disassemble the equipment, ship it to the company's facility and assemble the equipment to the final configuration. This option is best recommended for projects of such scope because it combines the best use of company's resources with the expertise of the vendors.

The Integration option is used in smaller projects where only a partial line may be installed or rebuilt. In this situation, the company will be responsible for everything involving the purchase of the equipment. The vendor will only be used to provide final installation/assembly of the machines at the company's site. Although checkouts of the individual equipment will be performed (by DuPont Merck's resources) prior to installation, this option does not allow for testing of the equipment as a system before they are integrated together. Hence, FAT test will not be performed.

The types of integration services should be evaluated and considered early in the process The company should begin assessing and evaluating the individual equipment which can meet the minimum design speed and also perform the necessary functions so that the best decisions could be made regardless of which integration services is used.

There are too many ways to describe the decision making process in assessing packaging equipment. Factors such as past experience with the particular equipment brand or type; suitability of the equipment to the particular process; the ease of changeovers or the cost of changeparts; accessibility to technical support or technicians from the vendors during an emergency; the equipment safety (Occupational Safety and Health Administration rules); and cleanliness (cGMP) features of the equipment; cost, quality and reliability of the equipment. These factors and many more make the decision particularly difficult. However, the major consideration should be the machine's ability to meet the design speed criteria of the packaging line.

Before any final decisions on the equipment are made, there is one more problem to investigate. This is the space limitation problem: Where do we install this line? For this

project, the issues relating to facility expansion was actually investigated concurrently with all of the previous activities described. However, this portion of the project was the result of the cooperation from all departments in the company; especially the company's architect, Mr. Sterling Kline.

CHAPTER 6 - FACILITY EXPANSION

CURRENT SITUATION

As discussed in the introduction, increasing activities in the Garden City site has resulted in a space issue. The current packaging area consists of five packaging lines with absolutely no room for expansion. The adjacent areas are occupied by manufacturing (compression and coating rooms), maintenance (boiler and parts room), labeling services and warehousing. All of these operations are located in the basement of the site. There is also no space available on the upper floors, which are occupied by manufacturing (weighing, mixing, granulation, rooms), quality control labs, clinical packaging (which is part of the R&D division), and offices for all site personnel. All available space has been reserved for the additional manufacturing and equipment required for the new AIDs drug. Furthermore, the local zoning laws will not permit further expansion of the site.

The capacity issues and the alternatives available to the site forced the issue of facility expansion to be investigated. This chapter will summarize the results of the facility expansion study performed by the company's architect, Mr. Sterling Kline. Mr. Kline was brought to the site from the corporate headquarters to work with facility and packaging engineering to assess the situation and provide recommendation.

FACILITY EXPANSION RECOMMENDATION

This project will not provide a complete description of the process in which the final recommendation was made. It will provide a brief explanation of the outcome:

- Architectural expansion of the current packaging area was not feasible due to the limited space that it currently faces.
- The use of manufacturing and maintenance area was also not feasible because of two reasons -- the manufacturing area will be needed to support the extra capacity issues and the cost of relocating the boiler room will be too prohibitive.
- The labeling area was not feasible because label storage requires proper environmental and regulatory conditions. The room is also too small for any packaging line installation.
- Currently, warehousing operations occupies approximately half the site. In addition, there is a satellite warehouse approximately eight miles from the site that holds all long term storage (i.e., not required for another two weeks) of raw materials and packaging components. The warehousing space on the site is used for storage of finished goods and staging of materials required for the current manufacturing and packaging operations. With the expected capacity increase, demand for all materials will also be proportionately increased. Warehousing will eventually be affected. Hence, the solution to the problem relating to the expansion of the facility is to proceed with a complete satellite

warehousing operation. This recommendation allows not only for the expansion of the site for packaging operations but also for other uses such as manufacturing space since the space currently occupied by warehousing is significant. Staging area will still be available for materials that will be needed for current manufacturing and packaging operations.

The final result of the facility expansion study provides a packaging area in the North-East corner of the building where the high-bay area of the warehouse currently exists. The line will have a total length of approximately 190 ft; the width of the line has no significant impact on the area. However, there are concrete beams along each section of the building that provide structural support to the building. The packaging line has to be constructed with the length and the structural beam constraint in mind.

COST OF FACILITY EXPANSION

With the preliminary facility design provided by the expansion study, facility engineering was given the project of establishing a final design for the new packaging area and assessing the construction cost of the project. In addition, the cost of all related engineering systems such as utilities must be included in the total cost of the construction project.

Working with several construction firms experienced in the pharmaceutical industry, the final design and bids for the project were submitted. The total cost of the

project as submitted from the construction company of choice, Jacobs Engineering, is between the range of $1.9 million to $2.3 million, depending on the proposal chosen. Since the facility expansion/construction is required to satisfy the need for a new packaging line, the total cost of this project will have to be included in the cost of the new packaging line.

CHAPTER 7 - TOTAL COST OF PACKAGING LINE INVESTMENT

As discussed in Chapter 5, there are many factors that determine the choice of packaging equipment. Many vendors will have to be evaluated based on factors such as speed, costs, quality, functionality, timeliness, service and size of their equipment. Appendix I shows the costs breakdown of the packaging line and other associated costs such as capitalizable engineering services, travel (such as vendor visits, equipment checkouts and factory acceptance testing), materials and components for equipment testing, validation packages and integration services. Another important factor is the number of operators (direct labor) required to operate the line.

Once a general idea of the type, cost and size of the equipment is determined, the number of operators that will be required to run the line with each proposal can then be evaluated.

From the information provided by the facility expansion study, the line layout for the packaging area is achieved with the assistance of an integrator. In this case, the integrator used was DT Lakso. The use of an experienced pharmaceutical integrator to the layout of a packaging line is very important because of their expertise and experience in the design and installation of pharmaceutical packaging lines for other companies. Using the Functional Description document as the guide, the layout of Proposal C (the fully automated line scenario), is shown in Appendix J.

Using the fully automated line layout as a guide and the process flow charts of each scenario as shown in Appendix K to N (Current, Proposal A, B and C) , the number of operators required for each proposal can be evaluated together with the packaging line supervisor. The following shows the number of operators that are required for Proposal A and B:

# of Operators	Process (Job Functions)
1	Floater - Supply bottles, desiccant and product to equipment in Proposal B.
2	Proposal A - 1 filler operator; 1 product filler. Proposal B - 1 filler operator to both fillers.
1	Floater/operator - Supply caps, labels, outserts to equipment and run capper.
1	Operator - Labeler.
1	Floater - Supply shrinkfilms, shippers, pallets to process.
3	Operator - Manually label bundle, erect, label, tape and palletize shipper.
1	Operator - Remove finish pallet for manual stretch-wrapping.
Total	10 operators

Proposal C will require:

# of Operators	Process (Job Functions)
1	Floater - Supply bottles, desiccant, product to equipment.
2	Operator - Fillers.
1	Floater - Supply caps, labels, outserts, films, shippers.
1	Operator - Capper, labeler and bundler.
Total	5 operators

COST BREAKDOWN OF EACH PROPOSAL:

From all the information gathered so far, the estimated cost of each proposal can be broken down. This will also allow the comparison of all the different alternatives that were investigated based on all the factors that were previously discussed. Furthermore, justification to the best solution can be made using cost accounting.

PROPOSAL A

EQUIPMENT/SERVICES	COST
PACKAGING EQUIPMENT	$3.0 million
FACILITY CONSTRUCTION	$1.9 million
TOTAL	$4.9 million

PROPOSAL B

EQUIPMENT/SERVICES	COST
PACKAGING EQUIPMENT	$3.4 million
FACILITY CONSTRUCTION	$2.1 million
TOTAL	$5.5 million

PROPOSAL C

EQUIPMENT/SERVICES	COST
PACKAGING EQUIPMENT	$4.0 million
FACILITY CONSTRUCTION	$2.3 million
TOTAL	$6.3 million

TIMELINE

As with any projects, the timeline or project schedule will have to be included into the cost and decision making process since delays in a schedule will increase the cost of the projects. Working with all the equipment vendors, and the facility engineer; a timeline of the project was proposed based on the actual approval of the project and the alternative chosen.

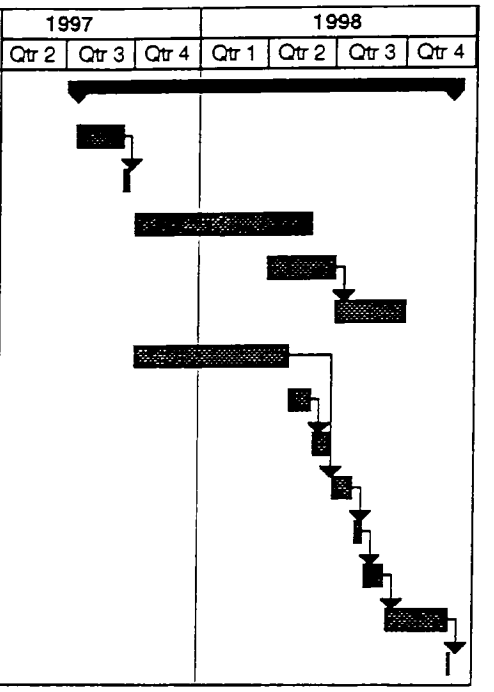
The timeline has to include several factors such as:

- The approval date of the project.
- The time required for facility modification and construction.
- The time required for all installation of engineering systems such as utilities.
- The clearance of the present warehouse for construction.
- The time required for packaging equipment fabrication.
- The time needed for all FAT test.
- The time needed to validate the new packaging area.
- The time required for equipment (engineering and packaging) validation.

Using the above criteria as a guidance, the timeline of the project was developed by all personnel involved in the Garden City site (packaging, engineering, validation, and quality). It was agreed that the whole project could be completed within fifteen months from the approval date of the project. Hence, if the project is approved in September 15, 1997, production can begin on the new packaging line on November 30, 1998. Table 8 shows the project schedule.

Table 8

Task Name	Start	Finish
Line 6 Project	7/15/97	11/30/98
Approve Cap. Auth.	7/15/97	9/15/97
Issue P.O.'s	9/16/97	9/24/97
Facility Construction	10/1/97	5/29/98
Utility Installation	4/1/98	6/30/98
Facility and Utility Validation	7/1/98	9/30/98
Equipment Construction	10/1/97	4/30/98
Machine Checkouts	5/1/98	5/29/98
Line Assembly at Integrator	6/1/98	6/26/98
Test Machines at Integrator	6/29/98	7/24/98
Line Acceptance (FAT) Testing	7/27/98	8/7/98
Crate/Ship/Receive/Assemble Machines at DMPC	8/10/98	9/4/98
Packaging Equipment Validation	9/7/98	11/27/98
Handover	11/30/98	11/30/98



CHAPTER 8 - JUSTIFICATION

There are many ways in which a company justifies the cost of investing in a project, equipment, or employees. The most common methods are based on financial analysis which provides a 'hard' or visible savings and cost to the company. Justification of projects could also be based on 'soft' or invisible savings although they are generally harder to justify. The difference between the two types of savings is its tangibility. Can the results be clearly seen?

Using Proposal B and C as examples, where both options will provide the same speed and total capacity to the site and also meet the demands, the automation of the line in Proposal C results in both types of savings. The reduction of labor from 10 operators to 5 operators is a form of hard savings. One could actually measure if the savings were achieved and hence the success of the project. In the 'soft' savings, one could argue that the automation of the process for manual packing, sealing, palletization and stretch-wrapping provides better ergonomics to the operation of the line. Furthermore, it provides the operators with a much safer working environment with less repetitive actions being performed. Hence, due to the automation of the process, less work time injury may occur. Since such savings could vary as it is based on the amount of injury time that might result from the manual process, one can only provide the best estimate.

In this study, the financial analysis is based on tangible savings that one could easily calculate with the help of the company's financial department. All information gathered has to be compiled and analyzed to financially justify the proposals. In the

previous chapters, assumptions were made to derive the total cost of labor, contract services (if required), and the incremental operating cost of each proposal. Table 9 summarizes the yearly total cost that the Garden City site would have to bear in the respective years to meet the demand as forecasted by marketing for each alternative investigated.

Table 9

YEAR	Current	Proposal A	Proposal B	Proposal C
1998	$1,246,560	$970,093	$791,518	$672,399
1999	$2,179,274	$805,738	$538,619	$374,309
2000	$4,399,943	$1,333,790	$929,932	$674,966
2001	$5,684,318	$2,386,182	$1,300,599	$990,299
2002	$6,690,301	$3,273,554	$1,484,097	$1,132,049
2003	$8,078,796	$4,658,492	$1,763,794	$1,351,897
2004	$8,844,495	$5,293,379	$1,928,477	$1,484,239
2005	$9,594,108	$5,925,384	$2,077,017	$1,598,508
Total	$46,717,795	$24,646,612	$10,814,053	$8,278,666

Using the table, the justification of the cost could be simplified. By comparing the total cost of each proposal against the current situation, the use of contract packaging services for a long period to meet the demands instead of expanding the current capacity of the site becomes a costly decision. To fully justify the project and determine the best alternative to the solution, a comparison of the savings against the cost to implement each proposal has to be studied. This method of financial justification is very common in the industry.

In this situation, most companies will compare the total costs of each proposal against the current situation (i.e., the savings that will be obtained against the total project cost of each proposal).

For example, the savings that will be obtained by comparing the yearly total cost of Proposal A against the current situation and the total project cost of the Proposal A to the savings will be the numbers that will be used to financially justify the project.

Table 10

YEAR	Current	Proposal A	Savings
1998	$1,246,560	$970,093	$276,467
1999	$2,179,274	$805,738	$1,373,536
2000	$4,399,943	$1,333,790	$3,066,153
2001	$5,684,318	$2,386,182	$3,298,136
2002	$6,690,301	$3,273,554	$3,416,747
2003	$8,078,796	$4,658,492	$3,420,304
2004	$8,844,495	$5,293,379	$3,551,116
2005	$9,594,108	$5,925,384	$3,668,724

Using the savings obtained in Table 10 and comparing the savings against the total project cost of Proposal A ($4.9 million), the project could be justified by performing cash flow analysis. This study will not explain the derivation of the cost flow analysis since different companies uses different methods of analysis. However, based on a capital depreciation for equipment of 8 years and 39 years for facility modification/expansion and a Present Value of 12%, the Internal Rate of Returns for Proposal A is 32% with a payback period of 2.5 years[9]. Hence, based on the financial analysis, Proposal A is a favorable project.

[9] Personal Communications, Financial Analyst, DuPont Merck Pharmaceuticals, Steve Kessler, Jun. '97.

In most companies, the project justification of this project would continue to be performed by comparing Proposal B and C with the current situation for savings followed by the same cash flow analysis method to compare the savings against the total cost of each proposal.

Due to management request and reasons that will not be disclosed in this study, the financial analysis of this study was carried out by comparing the options (i.e., Proposal A was compared against the Current situation, Proposal B against Proposal A, and Proposal C against Proposal B). In addition, the costs of each proposal were broken down to show the additional cost beyond Proposal A. For example, the implementation of Proposal B will require an additional $525,000 to the total project cost of Proposal A. The table below shows the costs breakdown of each proposal:

Table 11

PROPOSAL	EQUIPMENT COST	FACILITY COST	TOTAL
A	$3,000,000	$1,900,000	$4,900,000
B	$400,000	$125,000	$525,000
C	$600,000	$125,000	$725,000

Since the total cost of Proposal A was not changed, the results of the cash flow analysis as shown in the previous section remained the same. Again, using the same financial assumption of capital depreciation for equipment of 8 years and 39 years for facility modification/expansion and a Present Value of 12%, Table 12 summarizes the cash flow analysis of each proposal:

Table 12

Comparison	Project Cost	Project NPV	Internal Rate of Return	Payback Period
A to Current	$4,900,000	$3,993,706	32%	2.5 years
B to A	$525,000	$3,836,370	70%	2.9 years
C to B	$725,000	$305,496	21%	4.3 years

CHAPTER 9 - CONCLUSION

This study has been an attempt to justify the cost of investing in a packaging line at the Garden City site versus the cost of contract packaging. It will hopefully allow the reader to gain a perspective of the different tasks that may be involved in a project of this scope and also an opportunity to improve on the study. Assessing the current situation and improving the current process or method of operation should be the first step taken before investing too much time on such a project.

Management has been made aware of the critical capacity situation that the site is facing, and that immediate attention is required to allow the site to continue to operate without increasing the cost of manufacturing and packaging of all the products in the site. The impact of the new AIDs drug and the reliability of the forecast provided by Marketing cannot be confirmed until the product is launched. However, the demands for Cozaar and Hyzaar have continued to increase substantially in the last two years since their launch. Hence, the increase in production demand is very real and it is the manufacturing site's responsibility to meet the demand while keeping costs manageable.

Finally, as for the recommendation to the alternatives investigated, this study has shown the following:

- A third shift is required by the end of 1998 to meet projected demands. Operators will have to be hired and trained several months prior to the implementation.

- The use of a contract packager will be required if no additional capacity is added to the site.
- The cost of contract packaging is not favorable compared to the cost of any of the proposals to develop additional production capacity. Unit costs will be reduced substantially as a result of implementing any of the proposed alternatives.
- The reliability of the current Line 2 is questionable and the possibility of a major breakdown or significant downtime on the line must be acknowledged. Future production capacity may be adversely affected if nothing is done to the line.
- Proposal B provides the best Internal Rate of Returns with 70% and also provides the capacity to meet demands.
- Proposal C allows the reduction of direct labor on the line and hence unit cost.
- The timeline of this project is fifteen months from the approval date. Any delay in the decision will affect the startup date of the project and may also affect the cash flow analysis of the project.

This study proposes that management provide the funding required for the installation of the line as shown in Proposal C. The investment will result in the ability of the site to meet all anticipated demands through 2005. It will greatly reduce the unit cost

of the bottle and yet continue to provide for quality products using the least amount of hand labor. It will allow management to delay the improvements required on Line 2 and lower the risk of not meeting demands, and most importantly, it avoids the need for contract packaging which greatly increases the manufacturing cost of the product.

APPENDIX A

Line 6 Alternatives - Current Capacity Chart

Appendix A - Line 6 Alternative - Current Capacity Chart

Line 6 Alternatives

Current LROP Demand (in 1000's)		97 6170	98 9500	99 12600	2000 18800	2001 22000	2002 24000	2003 27000	2004 28000	200 2900
Current Line 2 & 3 Capacity at 3 shifts / 5 days week	**# of bottles produced/day = 54,000**	10800	10800	10800	10800	10800	10800	10800	10800	1080
	number of days to meet demand	114	176	233	348	407	444	500	519	53
	# of shifts to meet demand	343	528	600	600	600	600	600	600	60
	Cost of labor/shift (Inflation=1.04)	$2,016	$2,097	$2,181	$2,268	$2,358	$2,453	$2,551	$2,653	$2,75
	Cost of labor to meet demand	$691,040	$1,106,560	$1,308,303	$1,360,635	$1,415,061	$1,471,663	$1,530,530	$1,591,751	$1,655,42
	Total # btls to be contracted	-4630	-1300	1800	8000	11200	13200	16200	17200	1820
	Contracted - Price/1000 btls	$298	$310	$322	$335	$349	$363	$377	$392	$40
	Inflation Rate = 1.04									
	Total Cost - Contracted	$0	$0	$580,170	$2,681,676	$3,904,520	$4,785,826	$6,108,454	$6,744,940	$7,422,57
	Incremental Operating Cost (IOC)	$0	$140,000	$290,800	$357,632	$364,737	$432,812	$439,812	$507,804	$516,11
	Total Labor/Contract Services/IOC	$691,040	$1,246,560	$2,179,274	$4,399,943	$5,684,318	$6,690,301	$8,078,796	$8,844,495	$9,594,10
	Total Cost per Bottle	0.112	0.131	0.173	0.234	0.258	0.279	0.299	0.316	0.33

APPENDIX B

Cozaar BOM

A[illegible]

Title:	Pg 1 of 5	Doc No: 5416
COZAAR® 50 MG TABLETS - 90'S	Superseded: 07/09/96	Version: 8
		Effective: 05/29/97
Destination: DOMESTIC	NDC:0006-0952-54 PSF: 3613-54-00	

Documentation Approval:	PRG: MANUFACTURING ENGINEERING	Doc Type: BILL OF MATERIALS

DESCRIPTION: Ninety (90) Cozaar® 50 mg tablets packaged in a plastic bottle with a plastic child resistant cap and labeled. Affix outsert to back of bottle. Twelve (12) bottles shall be bundled, perforated between sections and labeled on 1/2 of bundle section. Twelve (12) bundles shall be packed in a 2 x 2 x 3 configuration into a labelled corrugated shipper.

Component #	Description	Quantity	Unit of Measure
MR-0952*	Cozaar® Tablet, 50 mg, Green, Teardrop	90	ea
4684	Bottle, 75 cc, White, Round, Quantum	1	ea
8418	Cap, 2-Piece C/R, Plastic/Plastic, 33/400	1	ea
9733	Label, Pressure Sensitive, Two-Part	1	ea
6368	Outsert, Folded	1	ea
9340***	Tape, Outserter, 1"	0.0416	yd/ea
9309	Shrink Film, Polyethylene, 10-1/2"	0.001	lb/ea
9763	Sticker, Bundle	1/12	ea
8162	Shipper, Corrugated	1/144	ea
9334**	Tape, 2", Clear, Printed, Polypropylene	0.0081	yd/ea
9688	Sticker, Bar Code, Shipper	1/144	ea
9363	Pallet, 48" x 40", 4-way, Heavy Duty	1/4320	ea
ALTERNATE			
0952-00*	Cozaar® Tablets, 50 mg, Bulk Drum	0.0018	ea
9330**	Tape, 2", Clear, Printed, Polypropylene	0.0081	yd/ea
9304***	Tape, Outserter, 1-1/4"	0.0416	yd/ea

NOTES: Palletize on 40" x 48" pallet in 10 shippers/layer, 3 layers high.
Expiration Dating: 24 mos.

APPENDIX C

Hyzaar BOM

Title:	Pg 1 of 5	Doc No: 5406
HYZAAR™ 50-12.5 MG TABLETS - 90'S	Superseded: 07/09/96	Version: 8
		Effective: 05/29/97
Destination: DOMESTIC	NDC:0006-0717-54 PSF: 3502-54-00	

Documentation Approval:	PRG: MANUFACTURING ENGINEERING	Doc Type: BILL OF MATERIALS

DESCRIPTION: Ninety (90) Hyzaar™ 50-12.5 mg tablets packaged in a plastic bottle with a plastic child resistant cap and labeled. Affix outsert to back of bottle. Twelve (12) bottles shall be bundled, perforated between sections and labeled on 1/2 of bundle section. Twelve (12) bundles shall be packed in a 2 x 2 x 3 configuration into a labelled corrugated shipper.

Component #	Description	Quantity	Unit of Measure
MR-0717*	Hyzaar™ Tablet, 50-12.5 mg, Dark Yellow, Teardrop	90	ea
4684	Bottle, 75 cc, White, Round, Quantum	1	ea
8418	Cap, 2-Piece C/R, Plastic/Plastic, 33/400	1	ea
9734	Label, Pressure Sensitive, Two-Part	1	ea
6369	Outsert, Folded	1	ea
9340***	Tape, Outserter, 1"	0.0416	yd/ea
9309	Shrink Film, Polyethylene, 10-1/2"	0.001	lb/ea
9763	Sticker, Bundle	1/12	ea
8162	Shipper, Corrugated	1/144	ea
9334**	Tape, 2", Clear, Printed, Polypropylene	0.0081	yd/ea
9688	Sticker, Bar Code, Shipper	1/144	ea
9363	Pallet, 48" x 40", 4-way, Heavy Duty	1/4320	ea
ALTERNATE			
0717-00*	Hyzaar™ Tablets, 50-12.5 mg, Bulk Drum	0.0036	ea
9330**	Tape, 2", Clear, Printed, Polypropylene	0.0081	yd/ea
9304***	Tape, Outserter, 1-1/4"	0.0416	yd/ea

NOTES: Palletize on 40" x 48" pallet in 10 shippers/layer, 3 layers high.
Expiration Dating: 24 mos.

APPENDIX D

Incremental Operating Cost Calculation

Appendix D

Incremental Operating Costs of Line 6 due to increase in demands

Yearly Demands in mm	9500	12600	18800	22000	24000	27000	28000	29000
Change in demand	0	3100	6200	3200	2000	3000	1000	1000

Current Capacity requires 3 shifts.

Incremental Operating Cost	1998	1999	2000	2001	2002	2003	2004	2005
Fixed Headcount @ $60m/head w/benefits	$120,000	$120,000	$180,000	$180,000	$240,000	$240,000	$300,000	$300,000
*Incremental Operating Expense	$0	$150,000	$156,000	$162,240	$168,730	$175,479	$182,498	$189,798
Utilities for 3rd Shift	$20,000	$20,800	$21,632	$22,497	$23,397	$24,333	$25,306	$26,319
Total Incremental Op. Cost	$140,000	$290,800	$357,632	$364,737	$432,127	$439,812	$507,804	$516,116

Proposal A (20.5mm btls capacity) 3rd shift begins from year 2000

Incremental Operating Cost	1998	1999	2000	2001	2002	2003	2004	2005
Fixed Headcount @ $60m/head w/benefits	$0	$60,000	$120,000	$330,000	$330,000	$390,000	$390,000	$450,000
*Incremental Operating Expense	$0	$150,000	$300,000	$500,000	$600,000	$700,000	$800,000	$800,000
Utilities for 3rd Shift	$0	$20,800	$21,632	$22,497	$23,397	$24,333	$25,306	$26,319
Total Incremental Op. Cost	$0	$230,800	$441,632	$852,497	$953,397	$1,114,333	$1,215,306	$1,276,319

Proposal B (35.8mm btls capacity)

Incremental Operating Cost	1998	1999	2000	2001	2002	2003	2004	2005
Fixed Headcount @ $60m/head w/benefits	$0	$60,000	$120,000	$180,000	$180,000	$240,000	$240,000	$320,000
*Incremental Operating Expense	$0	$150,000	$300,000	$500,000	$600,000	$700,000	$800,000	$800,000
Utilities for 3rd Shift	$0	$0	$0	$0	$0	$0	$0	$0
Total Incremental Op. Cost	$0	$210,000	$420,000	$680,000	$780,000	$940,000	$1,040,000	$1,120,000

* Incremental Operating Expense include - Packaging, Warehouse, Building Services, etc.

**Proposal C will be the same as B.

NOTE: In Proposal B & C, no 3rd shifts will be required as the requirements will be met by packaging aligning itself to 10 hrs shifts, hence, there will be no utilities considered for the 3rd shift in the proposal and also less headcount.

APPENDIX E

Line 6 Alternative - Proposal A Capacity Chart

Appendix E - Line 6 Alternative - Proposal A Capacity Chart

Line 6 Alternatives

Current LROP Demand (in 1000's)		97 6170	98 9500	99 12600	2000 18800	2001 22000	2002 24000	2003 27000	2004 28000	2005 29000
Proposal A - Capacity at 3 shifts / 5 days week	**# of bottles produced/day=102,400**	20500	20500	20500	20500	20500	20500	20500	20500	20500
Bottle supply/cleaning, 1 fillroom, capper, labeler w/auto outsert feed system, bundler; manual casepacking and palletizing with no pallet stretchbanding capability - $3.0mm	**number of days to meet demand**	60	93	123	184	215	234	264	273	283
	# of shifts to meet demand	181	278	369	551	600	600	600	600	600
	Cost of labor/shift (Inflation=1.04)	$1,440	$1,498	$1,558	$1,620	$1,685	$1,752	$1,822	$1,895	$1,971
	Cost of labor to meet demand	$260,297	$416,813	$574,938	$892,158	$1,010,758	$1,051,188	$1,093,236	$1,136,965	$1,182,444
Proposal A cost = $3.0mm	**Total # btls to be contracted**	-14330	-11000	-7900	-1700	1500	3500	6500	7500	8500
	Contracted - Price/1000 btls	$298	$310	$322	$335	$349	$363	$377	$392	$408
	Inflation Rate = 1.04									
NOTE: Line 6 will not be ready till 7/98, hence assumption is made that 1/2 of 1998 demands will be packaged on Lines 2&3, adding labor cost in 1998 by $553,280.	**Total Cost - Contracted**	$0	$0	$0	$0	$522,927	$1,268,969	$2,450,923	$2,941,108	$3,466,585
	Incremental Operating Cost (IOC)	$0	$0	$230,800	$441,632	$852,497	$953,397	$1,114,333	$1,215,306	$1,276,319
	Total Labor/Contract Services/IOC	$260,297	$970,093	$805,738	$1,333,790	$2,386,182	$3,273,554	$4,658,492	$5,293,379	$5,925,348
	Total Cost per Bottle	0.042	0.102	0.064	0.071	0.108	0.136	0.173	0.189	0.204

APPENDIX F

Line 6 Alternative - Proposal B Capacity Chart

Appendix F - Line 6 Alternative - Proposal B Capacity Chart

Line 6 Alternatives

Current LROP Demand (in 1000's)		97	98	99	2000	2001	2002	2003	2004	2005
		6170	9500	12600	18800	22000	24000	27000	28000	29000
Proposal B Capacity		35800	35800	35800	35800	35800	35800	35800	35800	35800
at 3 shifts / 5 days week	# of bottles produced/day=179,155									
2nd fillroom added to Proposal A;	number of days to meet demand	34	53	70	105	123	134	151	156	162
Proposal B cost = $0.4mm	# of shifts to meet demand	103	159	211	315	368	402	452	469	486
	Cost of labor/shift (Inflation=1.04)	$1,440	$1,498	$1,558	$1,620	$1,685	$1,752	$1,822	$1,895	$1,971
	Cost of labor to meet demand	$148,778	$238,238	$328,619	$509,932	$620,599	$704,097	$823,794	$888,477	$957,017
	Total # btls to be contracted	-29630	-26300	-23200	-17000	-13800	-11800	-8800	-7800	-6800
NOTE: Line 6 will not be realy till 7/98,	Contracted - Price/1000 btls	$298	$310	$322	$335	$349	$363	$377	$392	$408
hence assumption is made that 1/2 of	Inflation Rate = 1.04									
1998 demands will be packaged on	Total Cost - Contracted	$0	$0	$0	$0	$0	$0	$0	$0	$0
Lines 2&3, adding labor cost in 1998										
by $553,280.	Incremental Operating Cost (IOC)	$0	$0	$210,000	$420,000	$680,000	$780,000	$940,000	$1,040,000	$1,120,000
	Total Labor/Contract Services/IOC	$148,778	$791,518	$538,619	$929,932	$1,300,599	$1,484,097	$1,763,794	$1,928,477	$2,077,017
	Total Cost per Bottle	0.024	0.083	0.043	0.049	0.059	0.062	0.065	0.069	0.072

APPENDIX G

Line 6 Alternative - Proposal C Capacity Chart

Appendix G - Line 6 Alternatives - Proposal C Capacity Chart

Line 6 Alternatives

Current LROP Demand (in 1000's)		97 6170	98 9500	99 12600	2000 18800	2001 22000	2002 24000	2003 27000	2004 28000	2005 29000
Proposal C - Capacity		35800	35800	35800	35800	35800	35800	35800	35800	35800
at 3 shifts/5 days week	# of bottles produced/day=179,155									
adds casepacker, palletizer and	number of days to meet demand	34	53	70	105	123	134	151	156	162
stretchbanding capability to	# of shifts to meet demand	103	159	211	315	368	402	452	469	486
Proposal A	Cost of labor/shift (Inflation=1.04)	$720	$749	$779	$810	$842	$876	$911	$947	$985
Proposal C cost = $0.6mm	Cost of labor to meet demand	$74,389	$119,119	$164,309	$254,966	$310,299	$352,049	$411,897	$444,239	$478,508
	Total # btls to be contracted	-29630	-26300	-23200	-17000	-13800	-11800	-8800	-7800	-6800
	Contracted - Price/1000 btls	$298	$310	$322	$335	$349	$363	$377	$392	$408
NOTE: Line 6 will not be ready till 7/98,	Inflation Rate = 1.04									
hence assumption is made that 1/2 of	Total Cost - Contracted	$0	$0	$0	$0	$0	$0	$0	$0	$0
1998 demands will be packaged on										
Lines 2&3, adding labor cost in 1998	Incremental Operating Cost	$0	$0	$210,000	$420,000	$680,000	$780,000	$940,000	$1,040,000	$1,120,000
by $553,280.										
	Total Labor & Contracted Services	$74,389	$672,399	$374,309	$674,966	$990,299	$1,132,049	$1,351,897	$1,484,239	$1,598,508
	Total Cost per Bottle	0.012	0.071	0.030	0.036	0.045	0.047	0.050	0.053	0.055

APPENDIX H

Function Description of Packaging Line 6

FUNCTIONAL DESCRIPTION OF DUPONT MERCK PHARMACEUTICAL PACKAGING LINE 6

I. INTRODUCTION:

This specification prepared to present the requirements for a high speed packaging line and to assist vendors in understanding the requirements of DuPont Merck. This document represents the functionality required, not necessarily the implementation. Any changes, modifications, deletions, exception, or interpretations must be approved by the DuPont Merck designated project engineer.

We ask that you retain these specifications in your files as the specification will be required to comprehend changes as they develop.

II. PROJECT OBJECTIVE:

The project objective is to package lot sizes of four million tablets or capsules into bottles, at a net output of 180 bottles per minute. Tablet product count is 30, 90, 100 into 75 or 120cc round bottle. The capsule product count will be 30, 60, or 90 capsules into 75 and/or 150cc round bottles. The line shall be automated with the use of operators for monitoring, and product supply.

III. SCOPE:

The scope of this document includes the specification of process, and process requirements.

IV PROCESS:

Bottle Unscrambling
Bottles will come to the line in bulk, and automatically loaded into the machine hopper. The bottles will be inverted, and rinsed by ionized air blast, orientated upright and delivered via conveyor to the filling station.

Bottle Filling
The filling machine will fill with an accurate count for the specified quantity of product. Following filling, bottles are conveyed to the capper.

Bottle Capper
The caps are brought to the line in bulk, and fed to the machine via bulk hopper. The machine will place the cap onto the bottle to the specified removal torque.

Induction Sealing
The capped bottle will be inspected for foil and high or crooked caps. The bottle will then be conveyed to the induction unit and inspected for proper seal.

Retorquing
The bottles will then be retorqued to the proper removal torque range.

Labeling/Outserting
Bottles will be labeled with a pressure sensitive label. This label will require the date and lot coded to be printed on the label. An outsert will be attached to the bottle. The label and outsert will be inspected for the correct bar code. The label will also be inspected for correct expiration date and lot code.

Bundling/Labeling
The bottles will be orientated in groups of 3 X 4 for the 75cc/120cc and 2 X 3 for the 150cc bottles, and shrink wrapped. After wrapping, a label will be printed and apply to a bundle. once on the bundle the label presence must be verified.

Case Packing/Labeling
The bundles will be packed into shippers, and the shippers tapped closed. A corner label applied to the shipper, and the label presence verify. The shipper also will be coded with Revision Number (REV. 00) and sequential numbering (0001-9999) before palletization.

V. FUNCTIONAL REQUIREMENTS:

This section describes the specific functional requirements for the equipment and its integrated system. The vendor must comply with each of the following requirements:

A. Integration Requirements:

1. System must have the capability of a net output of 180 bottles per minute, at the end of the line.

2. The integrator must design all equipment to the 180 BPM net output over an eight hour shift.

3. The intergrator shall integrate all equipment with stainless steel raised bed conveyors.

4. The integrator shall incorporate variable speed control to ensure that the flow rate of product through the line can be regulated minimizing accumulated product at each piece of equipment.

5. The integrator shall assemble, wire, program, de-bug, and test run the line at integrators facility for the specified line speed (180 BPM net).

6. The integrator shall dismantle and prepare all equipment for shipment and make shipment arrangement.

7. The integrator must be prepared to receive, the crated equipment at DMPC Garden City site and place the equipment in its respective location on the line.

8. The integrator shall then assemble, wire, program, debug, test, and assist in validation of the line.

9. The integrator shall arrange to supply all documents necessary for training, startup, and support for the system.

10. Equipment must be capable of running all configurations described in Section VI.

11. Working direction of the line is from left to right.

12. The integrator shall submit, with quotation:
    - Scaled line layout drawings
    - A gantt chart will all major milestones, and critical paths identified (assume P.O issuance on June 2, 1997), and equipment completely installed and operational for validation at DMPC Garden City site on April 2, 1998.

B. Equipment Requirements

Bulk Feed: A feed system should automatically deliver, and dump bulk supply of 75cc, and 120cc HDPE bottles into a machine feed hopper. The feed system must be capable of three hours of production capacity, and provide notification when bulk storage remaining falls below a predefined level. The bulk feed system must also be capable of retaining the empty bulk container (Gaylord) that are leaving the feeding system.

NOTE: The feeding system shall be capable of being over-ridden if necessary for dumping of bottles directly into the hopper to facilitate regular shippers of bottles that are not supplied in bulk (Gaylords).

Bottle Unscrambler

Hopper: HDPE bottles dumped from bulk randomly into the floor level hopper. The hopper capacity provides for 15 minutes of production for all sizes of HPDE bottles at a rate of 360 bottles per minute. If a low level is reached a warning shall be given. A hopper cleanout door provides for purging unused bottles from the previous run.

Ionized Air Rinse: All HDPE bottles fed from the hopper are ionized air rinsed. Here a high velocity stream of ionized air is delivered to the interior of the inverted bottle. Any loose particles in the bottle are ionized, eliminating their ability to adhere to the inner surface of the bottle, and flow out of the bottle with the exhausting stream of ionized air.

Discharge Conveyor: The orientor will rotate the bottle to an upright position for delivery to the discharge conveyor. The discharge conveyor, while maintaining bottle orientation, will deliver the bottles to the filler conveyor.

Conveyor Guide Rails: All guide rails are to provide quick change for the next bottle size to be packaged.

Filler Conveyor: The filler conveyor provides for guiding the bottles through the tablet filler. Transferring of the bottles to the tablet filler, with all necessary bottle controls are to be part of the filler conveyor.

Tablet Filler: Tablets, capsules or caplets, for the designated product to be packaged, will be randomly dumped from a bulk hopper into a feed hopper of the filler. The tablet filler hopper, with auxiliary bulk shall have a capacity, or method of loading such that the machine will not be starved for product. The filler shall be capable of filling various counts of differing tablets, capsules or caplets, into various bottles. The necessary rate shall be 400 bottles per minute at a count of 100 for tablets; 175 bottles per minute for #0 capsules. All bottles leaving the filler shall have 100% accurate count.

Capper: The capper will cap the 75/120cc with 33mm finish and 150cc with 38mm finish HDPE bottles. The caps will all be screw type, plastic, plastic/plastic child resistant, metal, metal plastic over cap child resistant caps. Bottles will be fed along the conveyor to the capper bottle handling mechanism and maintained under the torque mechanism for the capping operation. Release torque of caps shall be within the specified range. The capper or the capper conveyor, must have a system to inspect and reject if necessary bottles with high, crooked, and missing caps.

Floor Level Hopper: The caps will be loaded in a floor level hopper which has a capacity for 1-1/2 hr supply time.

Hopper/Orienter: The caps are oriented and transferred to the cap track and to the escapement. While in the escapement, caps will be checked for the presence of the correct innerseal liner, (Foam or Foil). Any cap found not to have this liner will be rejected.

Induction Sealing: Foil seal capped bottles will require the system to verify that the bottle remained in the sealing zone for a correct amount of time. For incomplete sealing, the bottles in question must be removed from the line onto a reject tray, with verification. Should the problem persist the bottle flow into the sealing station must be stopped.

Retorquer: After induction sealing all foil sealed bottles shall be retorqued to specified release torque range.

Labeler: The labeler places pressure sensitive labels and outserts on all the above mentioned bottles. The labeler will code each label with human readable lot number, and expiration date on the label, for the 75/120cc bottles, two lot code/expiration date will be required on separate faces of the label. The labeler shall be capable of running continuously without stoppage while changing supply roll. It should be capable of accepting rolls of labels up to 18" OD, with a 3" ID, core. The outserts will be provided orientated from random bulk supply. The outserter shall run continuously for a minimum of 2 hours without being re-supplied.

Label Inspection Station: An inspection system will verify for the correct label and outsert bar code on the bottle. The inspection system will also verify that the correct lot code and expiration date are printed on the label. The labeler will have a default state of reject unless all critical information passes the inspections. Confirmation of rejected bottles will be required.

Bundler: The bundler will collate 75cc/120cc bottles in a 3 x 4 configuration and the 150cc in a 2 x 3 configuration. These configurations will be tightly constrained with shrink film. The bundle shall have a perforation splitting the bundle into halves.

Bundle Label Printer and Applicator: The label printer will print and apply a label with human readable and/or bar code information to the top of the bundle.

Bundle Reject: Incomplete bundle (wrong count) and bundle without label must be rejected.

Case Packer/Erector: The bundles shall be automatically placed into shippers. The shippers shall be taped top and bottom with Pressure Sensitive tape from supply roll of maximum 15" OD. The case packer shall have a 30 minute supply of shippers, and require no operator attention, other than loading of shippers.

Shipper Label Printer and Applicator: The label printer will print and apply a wrap-around corner label with human readable and/or bar code information to the shipper.

Shipper Printer: The shipper also will be coded with Revision Number (REV. 00) and sequential numbering (0001-9999) before palletization.

Palletizer: The palletizer shall take the shippers, and load them in a defined pattern on a skid . Once a Skid is fully loaded it shall be transferred from the load zone, to a stretch wrap. Upon completion of wrapping, the completed skid will be transferred to a staging area. An Operator will remove the completed skid from the staging area.

VI. COMPONENT & PRODUCT PROPERTIES:

A. Product Container Sizes

Container	Dia (in)	Ht (in)
75 cc	1.72"	3.00"
120 cc	1.87"	3.87"
150 cc	2.18"	3.68"

B. Tablet

Product	Ln (mm)	Wd (mm)	Tk (mm)	Shape	Color
Cozaar 25 mg	7.6 mm	4.7 mm	2.9 mm	Tear drop	Green
Cozaar 50 mg	9.35 mm	5.8 mm	3.55 mm	Tear drop	Green
Hyzaar 50/12.5 mg	11.1 mm	6.8 mm	4.25 mm	Tear drop	Yellow

C. Capsule

Product	Size	Color
Product A 100 mg	2	
Product B 150 mg	1	
Product C 200 mg	0 elongated	

D. Cap size, and type

Cap	Dia (mm)	Ht (in)	Inner Seal
CR	33mm	0.666	Foam
CR	38mm	0.705	Foil

E. Bottle Label Sizes

Ln (in) x Wi (in)
3-5/8" x 1-5/8"
3" x 2-1/4"

F. Outsert Sizes

Fold Dim (Ln x Ht): 1-1/2"x 2"

G. Printed and Apply Labels

	Bundle	Shipper
Bottle	Ln (in) x Wi (in)	Ln (in) x Wi (in)
150 cc	3-1/2" x 3-1/2"	10" x 4"
75 cc	3-3/4" x 2-3/8"	10" x 4"

H. Shipper

Shipper	Ln (in)	Ht (in)	Wd (in)
75 cc	15-1/4"	10-1/4"	11-3/4"
150 cc			

APPENDIX I

Equipment Cost

Estimated Equipment Cost

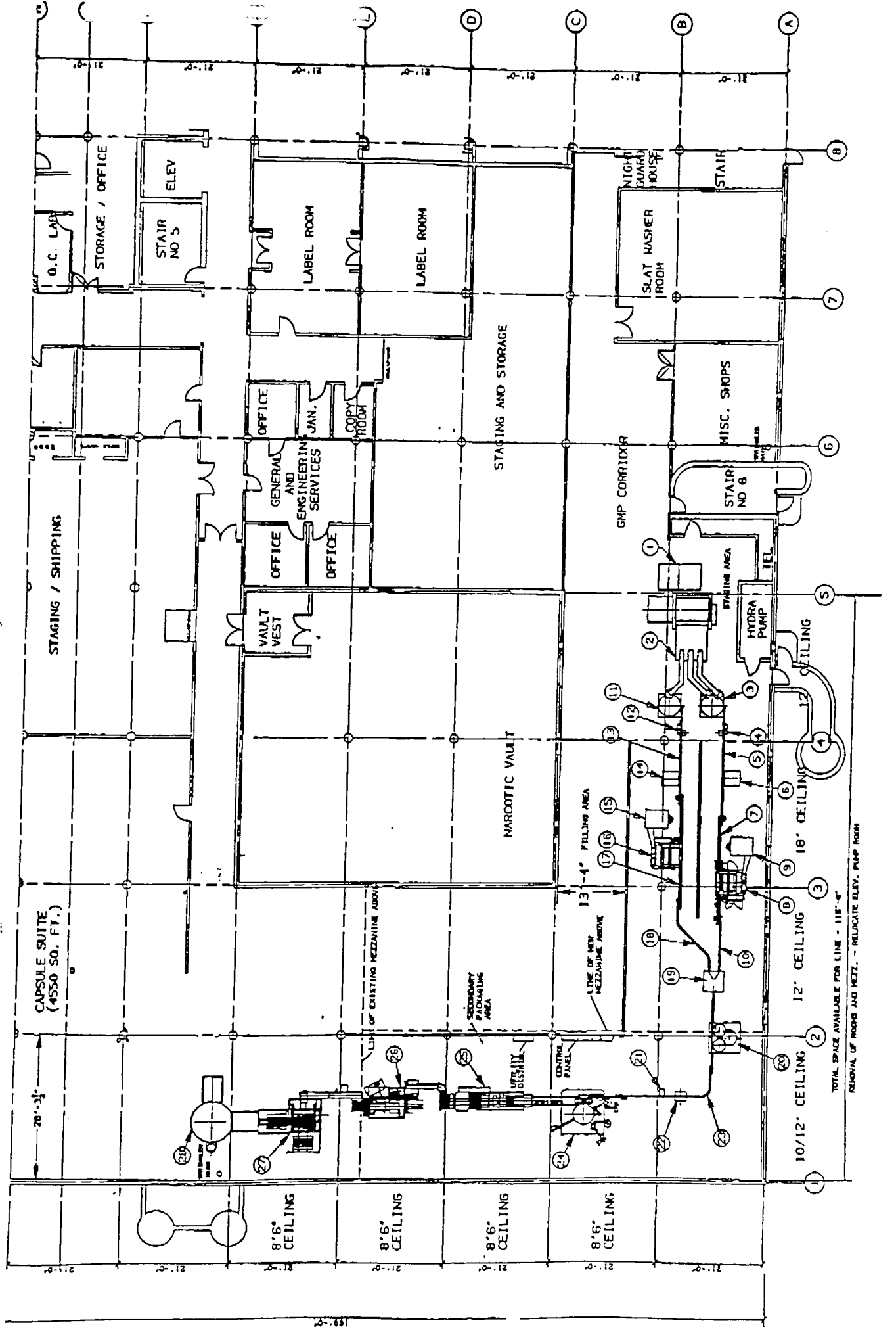
	Equipment	Cost
1	Bottle Feeder	150,000
2	Unscrambler A	150,000
3	*Unscrambler B	125,000
4	Desiccant Feeder A	55,000
5	Desiccant Feeder B	55,000
4	FIller A	450,000
5	Filler B	125,000
6	*Post Hoists	150,000
7	Capper	500,000
8	Bottle Ink Printer	30,000
9	Induction Sealer	30,000
10	Retorquer	25,000
11	Labeler	400,000
12	*Outsert Feed System	125,000
13	Bundler A	200,000
14	Bundler B	200,000
15	*Case Packer	200,000
16	*Palletizer	150,000
17	*Stretch Wrapper	50,000
18	Conveyors	150,000
19	Accumulator	50,000
20	Controls	100,000
21	Engineering	60,000
22	Travel	100,000
23	Components	60,000
23	Validation Packages	100,000
24	Installation/Integration	200,000
	Total	**3,990,000**

* Items not part of original scope of 11/96.

APPENDIX J

Line Layout

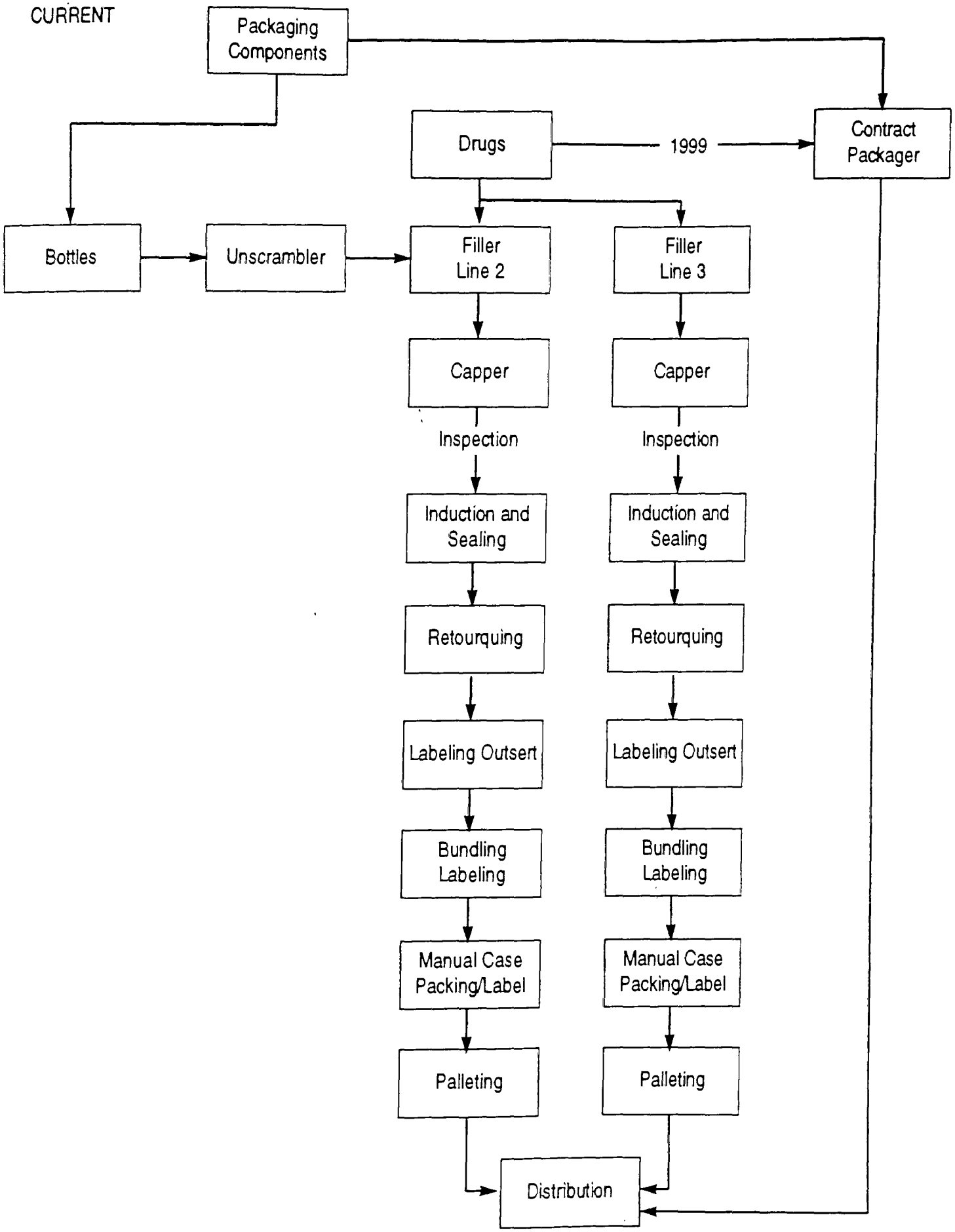
Appendix J - Line Layout



APPENDIX K

Process Flow Chart - Current

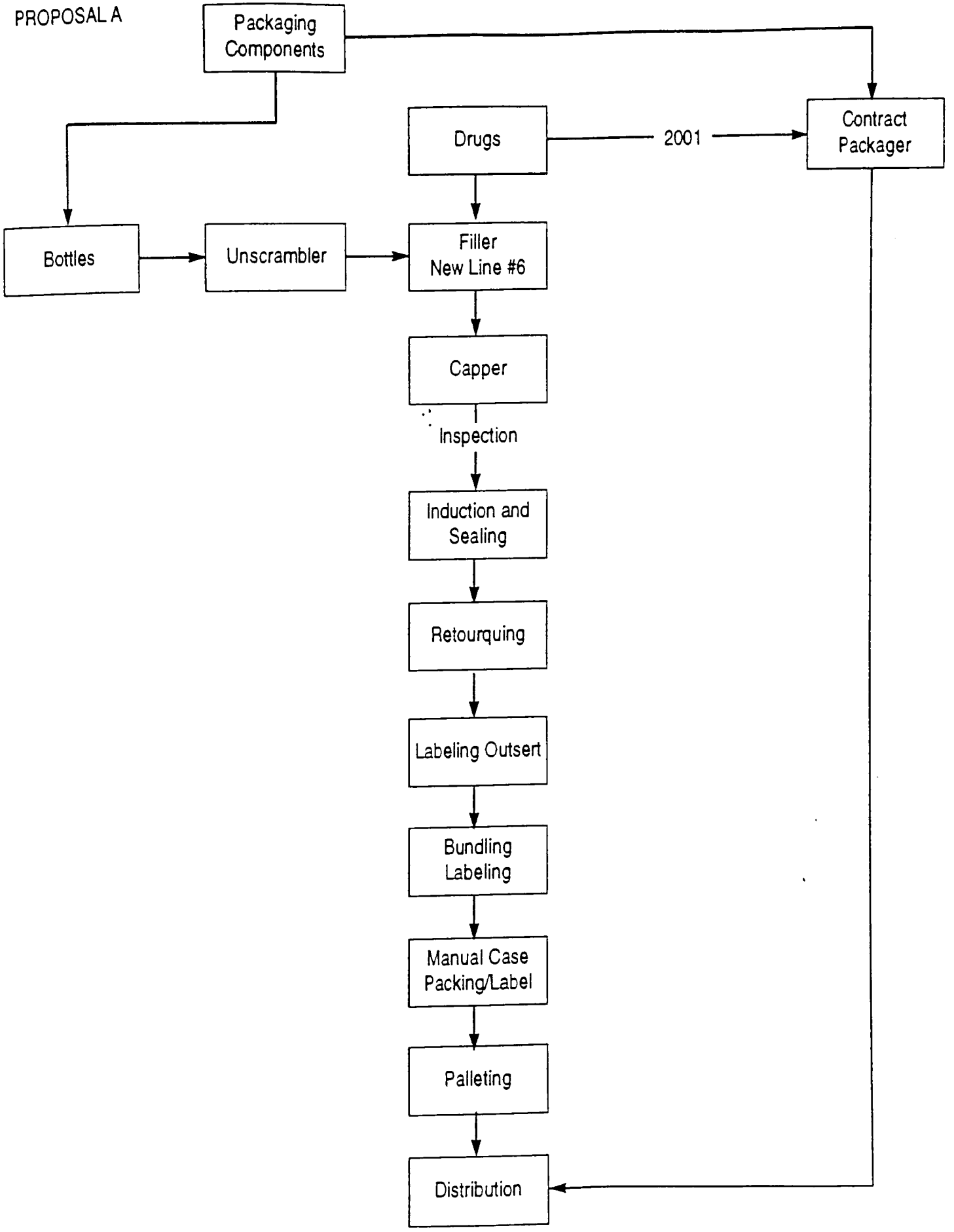
Appendix K - Process Flow Chart - Current



APPENDIX L

Process Flow Chart - Proposal A

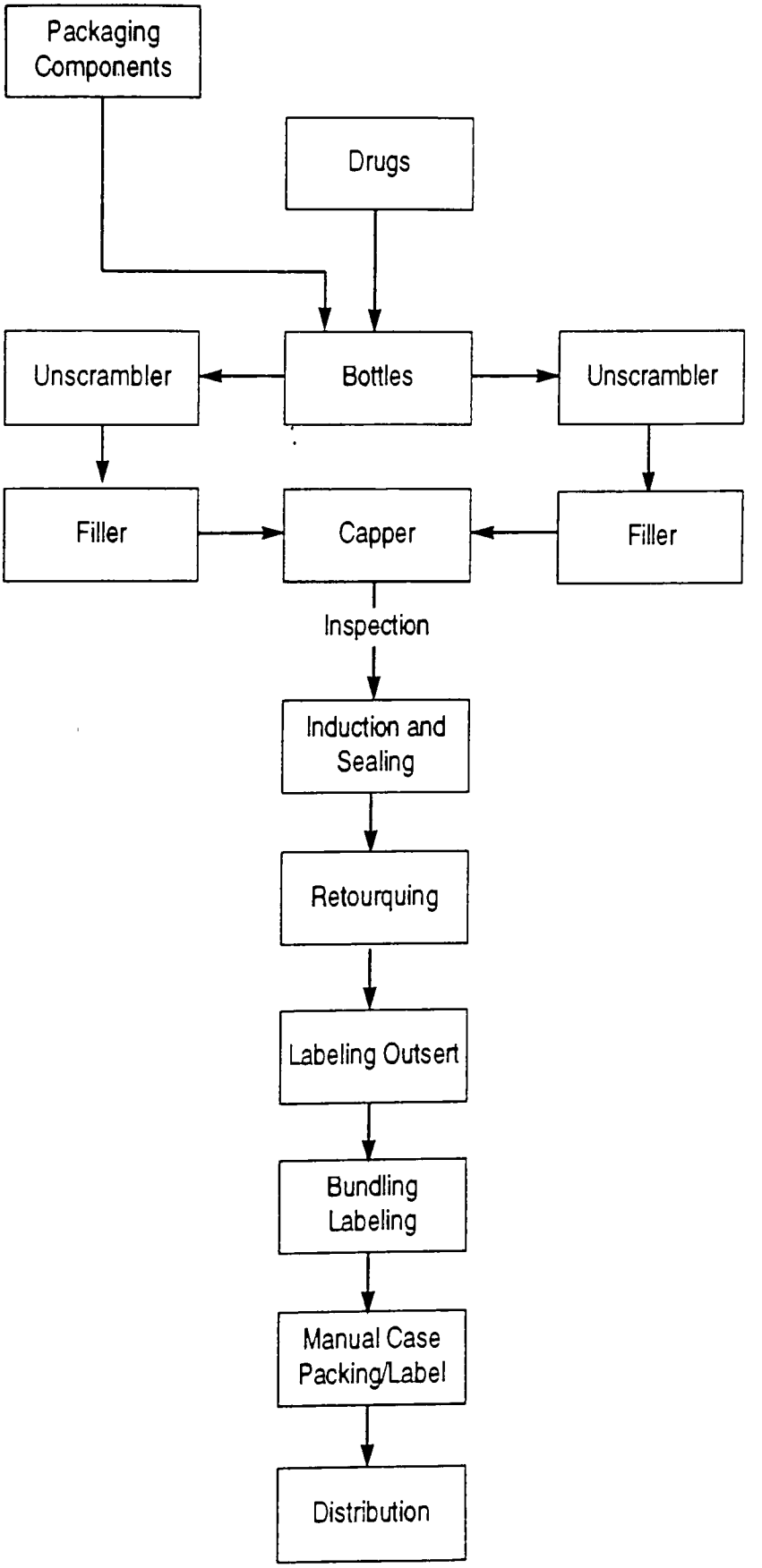
Appendix L - Process Flow Chart - Proposal A



APPENDIX M

Process Flow Chart - Proposal B

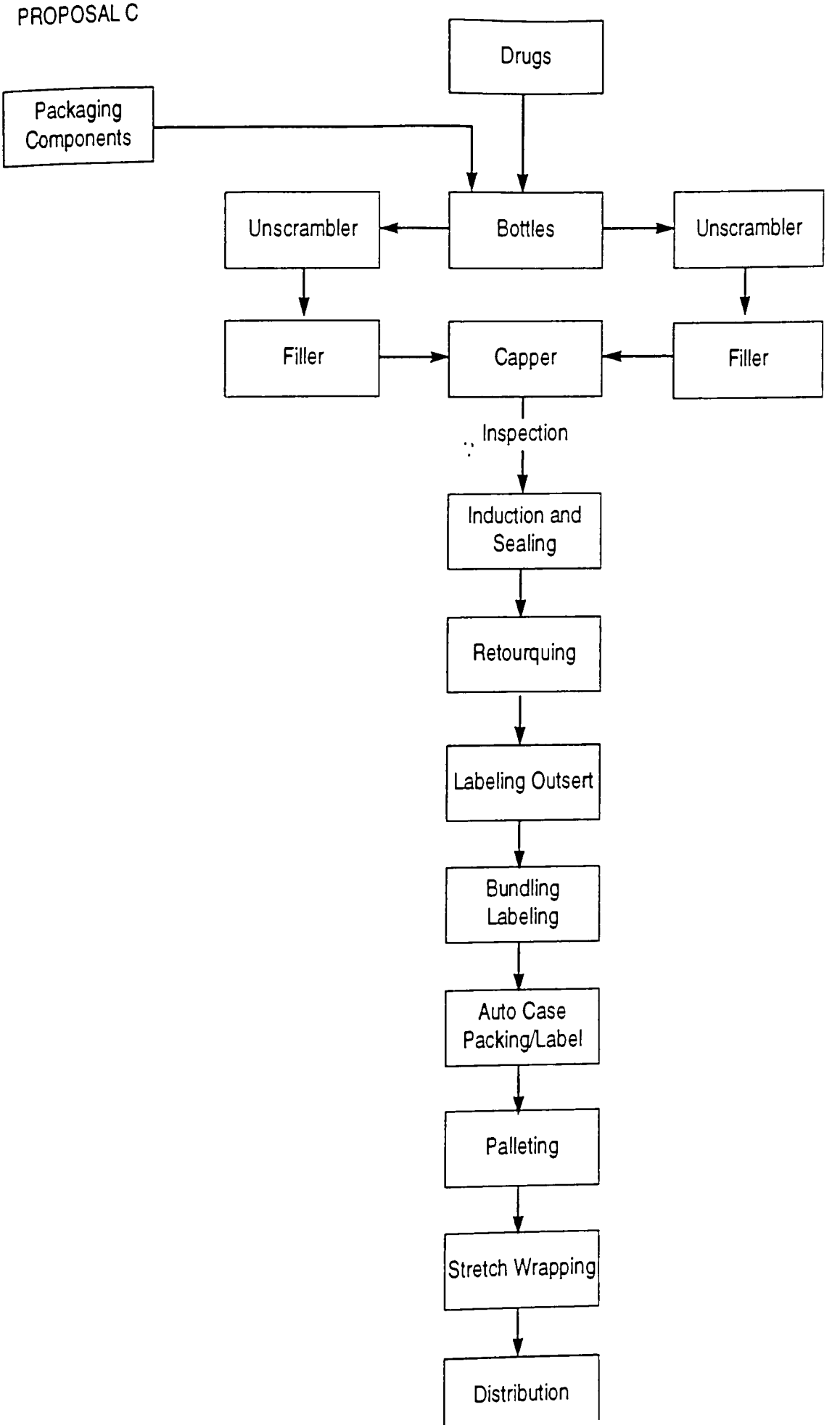
PROPOSAL B


Packaging Components
Drugs
Unscrambler
Bottles
Unscrambler
Filler
Capper
Filler
Inspection
Induction and Sealing
Retourquing
Labeling Outsert
Bundling Labeling
Manual Case Packing/Label
Distribution

APPENDIX N

Process Flow Chart - Proposal C

PROPOSAL C


Drugs
Packaging Components
Unscrambler
Bottles
Unscrambler
Filler
Capper
Filler
Inspection
Induction and Sealing
Retourquing
Labeling Outsert
Bundling Labeling
Auto Case Packing/Label
Palleting
Stretch Wrapping
Distribution

BIBLIOGRAPHY

1. Jenkins & Osborn, Packaging Drugs and Pharmaceuticals, Technomic Publishing Company, Inc., 1993, Pg. 14.

2. Lenny Lustrino, Personal Communications, Director of Facility and Engineering, DuPont Merck Pharmaceuticals, May 1997.

3. W. Soroka, Fundamentals of Packaging Technology, Institute of Packaging Professionals, Hendon, Virginia, 1995, Pg. 445.

4. Bill Lawton, Personal Communications, Technical Services Manager, DT Lakso, November 1996.

5. P Zeph, How to Analyze Packaging Line Performance, Institute of Packaging Professionals, Hendon, Virginia, 1993.

6. Jim Hills, Personal Communications, Vice-President, Operations, DT Lakso, January 1997.

7. Dave Burdan, Personal Communications, Sales & Technical Manager, Universal Machines, February 1997.

8. Tom Stange, Personal Communications, President, Automated Packaging System, December 1996.

9. Steve Kessler, Personal Communications, Financial Analyst, DuPont Merck Pharmaceuticals, June 1997.