



*JH Bertrand is a focused converter of products designed to expand copy space for multilingual, regulatory and promotional applications. Our facilities convert booklet labels and specialty tags for the medical, chemical, and consumer products industries.*

# JHBERTRAND INC

## **JH Bertrand offers innovative multilingual labeling solutions for limited space product containers.**

Pharmaceutical companies face a huge labeling challenge: how to fit multiple languages on products, particularly on small bottles and vials. Some of the smallest containers are less than an inch tall. To compound the problem, most languages take up 30% more space than English. The typical pharmaceutical company needs between 5-15 languages of patient information and instructions as their products move to global distribution. What can be done?

### **Readability should be the determining factor in your decision to reduce type size on labels.**

The most obvious solution is to reduce type fonts. This should be where companies start, but there are significant pitfalls. Small type faces are hard to read making it more difficult to understand. If the intended audience is older, small type could significantly lower comprehension. Reducing type from 8 to 6 point results in a 45% gain in space which is good for one language, but hardly makes a difference when companies need to add multiple languages for patient information and FDA-required warnings.

### **Abridging copy may create an FDA problem or potential product liability lawsuit.**

Writing the product label with simplicity in mind to save space is smart, but it can go too far. If the instructions are not adequately detailed or haven't followed FDA guidance, the patient or physician may misinterpret the label which may cause legal complications for both doctor and company. Medication errors

resulted in over 7000 deaths per year according to a study by the Institute of Health. Companies that don't follow FDA's label recommendations may be faced with recalls, product seizures or FDA lawsuits. The bottom line is that companies are required and expected to provide the most detailed label or face grave consequences.

### **Smaller product packaging is making the problem bigger.**

If multiple languages and growing FDA and patient instructions aren't complicated enough, the product container sizes are making the problem of fitting copy a lot more difficult. It is one thing if your product comes in a 750cc container that is 6-3/4" tall with a circumference of 11". It's quite another when it is a 6cc vial at 3/4" high with a circumference of 1-1/2". Single ply labels that size are too small to accommodate a meaningful amount of multilingual information.

### **JH Bertrand's focus is expanding label space.**

Over 25 years ago, we began our business servicing the agricultural chemical industry by manufacturing giant-sized booklet labels (averaging 6" x 6") to fit 2.5 gallon containers. Through the FIFRA Act (Federal Fungicide, Insecticide, Fungicide and Rodenticide), the EPA mandated that product labels have extensive and clear product use instructions. It wasn't uncommon for us to print a booklet label with 16 pages of first aid, application, and warning statements.

In the last 12 years, we moved our expertise to the pharmaceutical industry where the FDA requires drug manufacturers to provide extensive drug use instructions. A good example of an FDA mandate is in the January 18th, 2006 FDA report titled "New Prescription Drug Information Format to Improve Patient Safety." The FDA is now requiring drug manufacturers to organize the information more clearly by requiring a summary of the most important drug information and a table of contents on product labels.



*We are cGMP-compliant and follow strict SOPs. We have extensive procedures to maintain quality control, which include vision inspection, copy proof automation, cages, partitioned manufacturing, video surveillance, and bar code verification in a well organized, clean facility.*

Throughout the last 10 years, the FDA has required many of these mandates for ethical and OTC drugs which have dramatically increased the need for more label space. As the FDA required more drug detail, and drug manufacturers moved to globalization which required more languages on the product label, we refined our manufacturing processes to offer high quality tiny booklet labels.

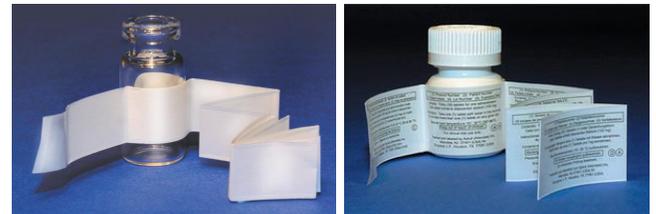
### **Introducing JHB's proprietary Micro-Miniature Booklet Labels (MMBL) ...a perfect solution for unit dose labeling.**

Our MMBLs are very small booklet labels designed to increase copy space by over 1,000% on products with small diameters. We can make our MMBLs as small as 1/2" x 1 1/2" with over 15 panels of copy. This translates into 30 pages of copy on 1/2" x 3/4" panels when both sides of each panel is printed.

Our MMBLs are manufactured following Current Good Manufacturing Practices (cGMP) and are of very high quality. We offset print (the highest quality printing) a pamphlet and coat it with two proprietary adhesives: one to keep the pamphlet permanently attached to the base label, and the other to make it easy to open. A non-adhesive extension on the cover of the pamphlet gives the end user something to grasp to start the opening process. We use coated or uncoated sheets and light weight papers from 60# coated to 27# uncoated. Our MMBLs should handle most small pharmaceutical containers.

### **The MMBL is a solution for the smallest diameters package...even vials.**

One of the best benefits of our MMBL is its ability to curve around small diameters. Because we glue the pamphlet to the base label rather than laminating it, our MMBLs can bend around very small diameters without the buckling you associate with laminated booklet labels. Buckling occurs on small diameters because the laminate holds its form and won't stretch beyond its original application on press. This results in a "bunching of material" at the leading edge of the label which is unattractive and may cause label



applicator jams. Our proprietary gluing process leaves the MMBL unrestricted to "mold around" the tightest diameters without causing buckling.

When companies want the laminated look, we can zone laminate the cover. We laminate the top cover without extending the laminate beyond the edge of the pamphlet which gives the "laminated look" without the restrictions of laminating.

### **Pharmaceutical companies can use their medical printers to control their MMBL projects.**

Most pharmaceutical companies have excellent, trusted medical printers that have handled the business for many years. We recognize this, so we offer pharmaceutical clients the opportunity to let their medical printers send us the printing for conversion into our MMBLs. This way, the printing is still controlled by the medical printer. JHBertrand is very good at partnering and recognizes the value that medical printers offer. When we partner with the medical printer, we become the highly skilled specialty finisher. This is a benefit for each party. The pharmaceutical company uses its medical printer to control the project. The medical printer keeps the business and strengthens its relationship with the



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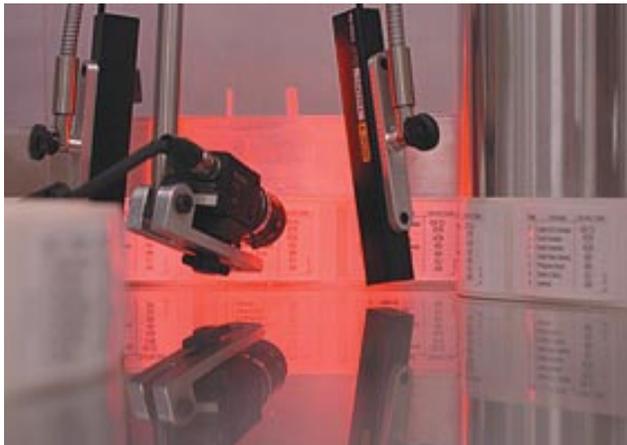


pharmaceutical company. And, JHBertrand becomes a valuable member of the team.

### JHBertrand embraces cGMP when manufacturing MMBLs.

Whether we deal directly with pharmaceutical companies or their medical printers, JHBertrand is set up to be a seamless extension of their facilities. JH Bertrand follows current good manufacturing processes (cGMP) with very detailed SOPs as defined by the FDAs CRF parts 210 and 211. We have extensive controls to make sure that there is never a label mix-up.

Inspections are conducted all through our process which includes incoming materials, converting and rewinding. Our rewinders (see picture below) have visual inspection and are run much more slowly than industry standards for better visual inspection. All materials for jobs are caged and discreetly labeled for privacy. Converting is done in small controlled rooms with video surveillance. JHB's production personnel wear scrubs while engaging with the product. Our facility is neat and our floors are clean. We are constantly updating and reviewing our quality systems. If we see anything that doesn't look right, we are quick to make the call to offer suggestions and ask the appropriate people what to do.



*We have a healthy R&D budget and experiment frequently. With 25 years of experience and low turnover, JHBertrand has the experience and talent to help with any specialty labeling requirements.*

### Developing an MMBL budget.

The following is the critical information we need to know to develop pricing:

- *Maximum size of booklet label to fit on container*
- *Copy submitted in word document with all languages using Ariel Unicode. (We can provide a copy fit estimate if the final approved copy isn't available.)*
- *Container size and diameter (Requires two empty samples.)*
- *Quantities*
- *Number of versions*
- *Number of colors on cover and inside (Indicate if graphics are needed.)*
- *Project deadline*
- *Application temperature*
- *Storage temperature*
- *Automatic or manual application*
- *Line speed of application*
- *Direction MMBLs should come off the roll*

*We make the process of creating an MMBL easy. After we receive the answers to the above questions and pricing is approved, we can make a template for your art department to fill out. Then we submit a PDF proof in about 2 days. With approval, we then provide film proofs in 3-4 days for final approval. After all proofs are approved, our manufacturing takes about 12-15 working days from the receipt of signed approved proofs.*

### JHBertrand offers a FREE no obligation Sample Kit.

To get started, please request a free sample kit by phone, fax, or register on our website. If the project is pending, please email us a document with the questions answered in the section: "What We Need To Know To Develop A MMBL Budget." We will include MMBLs and other products we make. We look forward to working on your multilingual project.

Thank you for considering JHBertrand.

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