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June 20, 2000

2129 '00 AUG 15 A9:49

Mr. Peter H. Cooney
Center for Drug Evaluation and Research (HFD-160)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. Cooney,

The Pascal Co., Inc is the manufacturer of an oral inhalant (called Breatheasy) which was specifically mentioned in the Federal Register's Final Rule (Vol. 65, No. 103 of May 26, 2000) concerning such products (page 34082).

As alluded to in the Register's text, we have been manufacturing Breatheasy since 1932. In the thirties, forties and fifties, it was one of the leading asthma relief products in the United States (the Pascal Co. was the first company to manufacture Racemic Epinephrine HCl commercially in the US). However, in the 1960's, the Pascal Co. switched its main marketing emphasis to the Dental field with a variety of other products, and stopped actively promoting Breatheasy. This was due to other asthma products coming out on the market that were more convenient to the end user, better advertised and more acceptable to the mass of the medical profession. By the 1990's, Pascal Co. had virtually ceased selling the product to drug wholesalers or drug stores. It has been our intention for the past 20 years to let the product slowly die out. That is why, from a business standpoint, the new Final Ruling will have minimal effect on our company since Breatheasy now represents around 0.2% (or \$10,000) of our total annual sales in 1999. Our projected sales in 2000 will be \$8300.

Our reason for continuing to sell the product has been as a service to our aging customer base. Most of these customers are very elderly and are intensely product loyal. They will insist that no other product provides them with relief, that they have used it for 40, 50 or 60 years without ill effect, and that "they just wouldn't know what to do without Breatheasy". When we informed them (perhaps unwisely) of this potential Ruling, and our inability to justify the expenditures to Pascal that its implementation would entail, we brought on a flood of impassioned letters and phone calls to our Customer Service department. Many of these people have called repeatedly and expressed extreme concern -- in all probability similar in tone to the 41 letters that the FDA received prior to the ruling.

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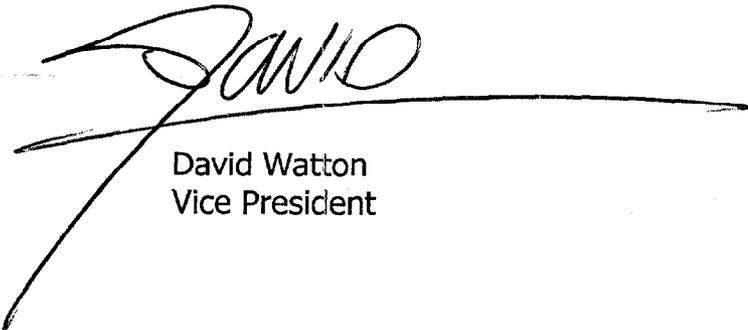
Our concern at this point is with this elderly clientele. Many of them are in their 70's, 80's and even 90's and will undoubtedly passionately resist having to change products. Rightly or wrongly, they are convinced that nothing else will work for them when they have an asthma attack. The product's relative cheapness (\$10.00 per ounce) in comparison to other similar products is also an important consideration for them.

We realize that it is pretty late in the game to be proposing this; that the ruling is now final and that it is extremely unlikely at this point that an exception can or will be made for an individual product. But we still felt we should make an attempt to propose to the FDA another possibility. So far in the year 2000, we have sold to a customer base of less than 100 people. Our total "active" customer list for Breatheasy is 222 (we "pruned" inactive customers off the list in 1997). Some of these customers may not presently be in a condition to place orders in the future. What we are proposing is permission to continue to sell to these long-time customers, but not be allowed to sell to any new ones. I am sure that such an action would be unusual -- but it might be one in the ultimate interest of the health and well being for a few people.

Please be assured that our motives for this letter are not for profit or in the interest of causing a problem for anyone. In all probability this proposal should have been made prior to the final ruling. We simply are concerned for the welfare of our long-time customers. We will of course abide by the ruling. Since we do not intend to buy the equipment to manufacture the product to be sterile, we plan at this point to cease selling the product as of April 30, 2002. We are assuming that we will be allowed to continue making the product as accustomed until then. Please let us know if this interpretation of the effective date of the ruling is correct.

Sincerely,

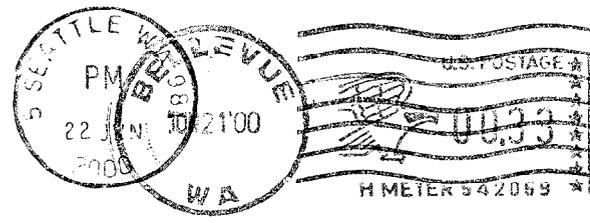
May 24, 2002

A large, stylized handwritten signature in black ink, appearing to read "D. Watton". The signature is written over a horizontal line that extends across the page.

David Watton
Vice President

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Company, Inc.

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