

SB
SmithKline Beecham
Consumer Healthcare

May 26, 2000

Documents Management Branch (HFA 305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

RE: Docket No. 00N-1256
FDA Regulation of OTC Drug Products Hearing

By copy of this memo, I am requesting 20 minutes to address the above referenced public hearing (Docket No. 00N-1256) to be held on June 28 and 29. I will be speaking on behalf of SmithKline Beecham Consumer Healthcare, L.P. as an authorized representative of the company.

I will be using the approval by FDA to switch Nicorette® smoking cessation gum from prescription to over the counter status as a case study to illustrate the tremendous public health benefit that can be achieved through the switch process. The Nicorette switch provides a practical example of how many of the issues under consideration at the hearing (evaluation of benefit/risk criteria, expanding definition of illness/disease, clinical/real-world measures of efficacy, public health benefits, and post marketing surveillance) can be evaluated and resolved. It is also an excellent example of going beyond traditional carton and bottle labeling to develop unique consumer education "vehicles" that provide treatment information and motivational support.

The approval of Nicorette in 1996 provides evidence of the importance of a case by case, data driven approach to switch. Nicorette is an example of industry and FDA working together in a collaborative fashion to define specific questions that needed to be answered when considering this switch. From these questions, a thorough and carefully designed research program was conducted which demonstrated that Nicorette was safe and effective for use in the OTC setting, and that appropriate labeling to provide for this safe and effective use could be developed. Thinking beyond approval, SmithKline Beecham also proposed and FDA accepted commitments for marketing practices and surveillance, again particular to switching a nicotine product.

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As a result of the switch of Nicorette and the other smoking cessation products that followed this initial approval, many more smokers who want to quit have had access to proven smoking cessation aids. The availability of these products as OTC's, coupled with the consumer advertising and promotion inherent in marketing over the counter products, has lead to a significant increase in the number of assisted quit attempts. Two articles, one published in the *Morbidity and Mortality Monthly Report*, and one published in *Tobacco Control* document the public health value of these switches. FDA and the companies involved can be justifiably proud of this public health benefit.

In considering its approach to Rx to OTC switch for the future, we suggest the Agency keep in mind the principles used to evaluate and approve Nicorette. It is a prime example of industry and FDA working collaboratively to introduce a new OTC therapeutic category. The result has been a significant benefit for the public health.

Sincerely,

A handwritten signature in black ink that reads "David Schifano for John Dent". The signature is written in a cursive style.

John Dent, Ph.D.
Vice President of Research and Development
SmithKline Beecham Consumer Healthcare, L.P.
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