PHARMACIA

Kathleen J. Day
Senior Director
Global Regulatory Affairs
Promotion & Labeling

Pharmacia Corporation
7000 Portage Road
Kalamazoo, Michigan 49001

telephone: (616) 833-8301
facsimile: (616) 833-8632
kathleen.j.day@pharmacia.com

May 18, 2001

Dockets Management Branch [HFA-350]
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket Number 01N-0078; Agency Information Collection Activities; Proposed Collections; Comment Request; Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer Promotion of Prescription Drugs (Federal Register: Volume 66, No. 53, March 10, 2001)

Dear Sir/Madam:

This response represents the collective comments from Pharmacia Corporation regarding the use of two proposed surveys that FDA intends to conduct in an effort to determine the impact of direct-to-consumer (DTC) promotion of prescription drugs. Our comments are provided in accordance with the request as stated in the Federal Register to submit written comments by May 18, 2001.

Pharmacia firmly endorses the belief that DTC advertising and promotion provides a beneficial service to consumers by providing them access to health care information about specific medical conditions and available treatment options. We believe DTC promotion facilitates discussions between health care professionals and patients, and treatment of the patient's medical condition.

While we appreciate the opportunity to provide comment on these surveys, we would like to point out that responding to the questions was a difficult task in light of the fact that the surveys in question were not published with the March 19, 2001 Federal Register Notice. Therefore, most of our comments are based on questions from the baseline survey conducted in 1999. We would also like to note that we did not have access to the proposed physician survey.

The following represents Pharmacia's response to the questions posed by the FDA:

1. *Whether the proposed collection of information is necessary for the proper performance of FDA's function, including whether the information will have practical utility.*

We agree that FDA has the responsibility to assess the impact of any guidance that it issues. Of course, the practical utility of any particular survey will depend on the quality of the survey. Moreover, we assert that the information obtained from these particular surveys be used in conjunction with other existing data sources in assessing whether any changes should be made to DTC advertising policy. Information obtained from surveys conducted by industry and consumer-oriented publications offer useful information that should be considered in any policy-making

decisions. For example, Prevention magazine conducted an in-depth assessment of DTC advertising in June 2000.

We recommend that any analysis or assessment of DTC advertising not rest solely on survey data. While survey data is best used to determine attitudes and beliefs of respondents, it may not necessarily accurately reflect actual consumer or physician behavior.

2. *The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and the assumptions used.*

FDA's stated objective, to evaluate the effects of the DTC guidance within 2 years of its finalization, is vague. Since the specific objectives and the test instrument were not described in the Federal Register Notice, we can only recommend that the FDA use a validated instrument to evaluate the survey data.

While the sample size of the proposed surveys is probably sufficient to draw some general conclusions, it is certainly not large enough for all necessary sub-group analyses. For example, if FDA wanted to look at the effect of DTC advertising on a particular subgroup or the impact of DTC advertising in a specific therapeutic category with a low population prevalence, then the overall sample size may not be sufficient to draw adequate sub-samples from which conclusions could be drawn.

3. *Ways to enhance the quality, utility, and clarity of the information to be collected.*

We recommend that FDA ensure that the line of questioning directed to patients and the specific methodology in the 2001 follow-up survey are consistent with those used in the 1999 baseline survey. This consistency is one of the measures necessary to accurately monitor any changes in attitudes and behavior of consumers.

We also recommend that the questions in the physician survey be specifically directed towards the impact DTC advertising has had on the physician's ***own*** practice, rather than pose questions that ask about general attitudes toward DTC advertising (e.g., physician attitudes towards appropriate DTC categories).

4. *Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.*

We advocate that the methodology (i.e., telephone surveys) used for the baseline survey conducted in 1999 be used to obtain information from the consumer and physician respondents in the 2001 survey to assure consistency. Allowing the use of different data collection technologies, such as the Internet, to obtain information with the follow-up survey would have a tendency to skew the results. For example, Internet respondents to the 2001 surveys would have more time to study the questions than did the baseline survey respondents. Further, since not all consumers/physicians have access to a computer and/or the Internet, this on-line methodology might inherently attract different kinds of respondents than would a telephone survey.

To minimize the burden of the collection of information from respondents, FDA should strongly consider eliminating the follow-up (mail) survey.

Pharmacia appreciates the opportunity to provide comment on these two proposed surveys and looks forward to continued dialogue with the FDA on DTC advertising issues.

Sincerely,

Sharon Phillips for

Kathleen J. Day

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