**PHARMACIA**

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July 13, 2001

Documents Management Branch [HFA-305]
Food and Drug Administration
5630 Fishers Lane, Rm.1061
Rockville, MD 20852

RE: Docket Number [01D-0162]; Draft Guidance for Industry on Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements; Availability (Federal Register: Volume 66, No. 78, April 23, 2001)

Dear Sir/Madam:

This response represents the collective comments from Pharmacia Corporation regarding the FDA Draft Guidance for industry entitled, "Using FDA-Approved Patient Labeling in Consumer-Directed Print Advertisements." Our comments are provided in accordance with the request as stated in the Federal Register to submit written comments by July 23, 2001.

Pharmacia welcomes the alternative to use FDA-approved patient labeling to fulfill the brief summary requirement in consumer-directed print advertisements. However, Pharmacia would like to make certain that the option of using other patient-directed prescription drug information to fulfill the brief summary requirement is also maintained (currently, industry often develops brief summaries in consumer language utilizing the approved physician labeling including the patient package insert for use in consumer print materials). Approved patient labeling may include information such as detailed instructions for use. This type of information may not be appropriate for a consumer that is merely considering the use of a particular drug and may detract from more important risk information. In other instances, the approved patient labeling may not be presented in a patient-friendly format. Therefore, reprinting the patient labeling exactly as approved (as described in the draft guidance), in some cases, may provide excessive unnecessary information or information that is not easily understood, thereby confusing the consumer. Pharmacia recommends that FDA continue to allow the use of patient-directed information other than the approved patient labeling as another option for those products with FDA-approved patient labeling suitable for use as a brief summary. Included in this alternative, would be the use of approved patient labeling that has been modified to delete information that may not be relevant for a brief summary, such as detailed instructions for use, or to add risk information that is not adequately addressed.

Pharmacia is in agreement with the draft guidance criteria for fulfilling the brief summary requirement, but is requesting clarification on one issue. Pharmacia is requesting an explanation of what is meant by the word "frequently" that is used to define side effects in the draft guidance under: III. Fulfilling the Brief Summary Requirement (see below).

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"FDA does not intend to object to the use of FDA-approved patient labeling to fulfill the brief summary requirement for DTC print advertisements if the labeling is reprinted in full and discusses in consumer-friendly language the following information from the advertised product's physician labeling:

•All other **frequently** occurring side effects that are likely to be drug related

*and...*

*Information from the product's approved physician labeling that need not be addressed in the FDA-approved patient labeling includes:*

•*Side effects that are not serious and do not occur **frequently** or that are unlikely to be the result of taking the product"*

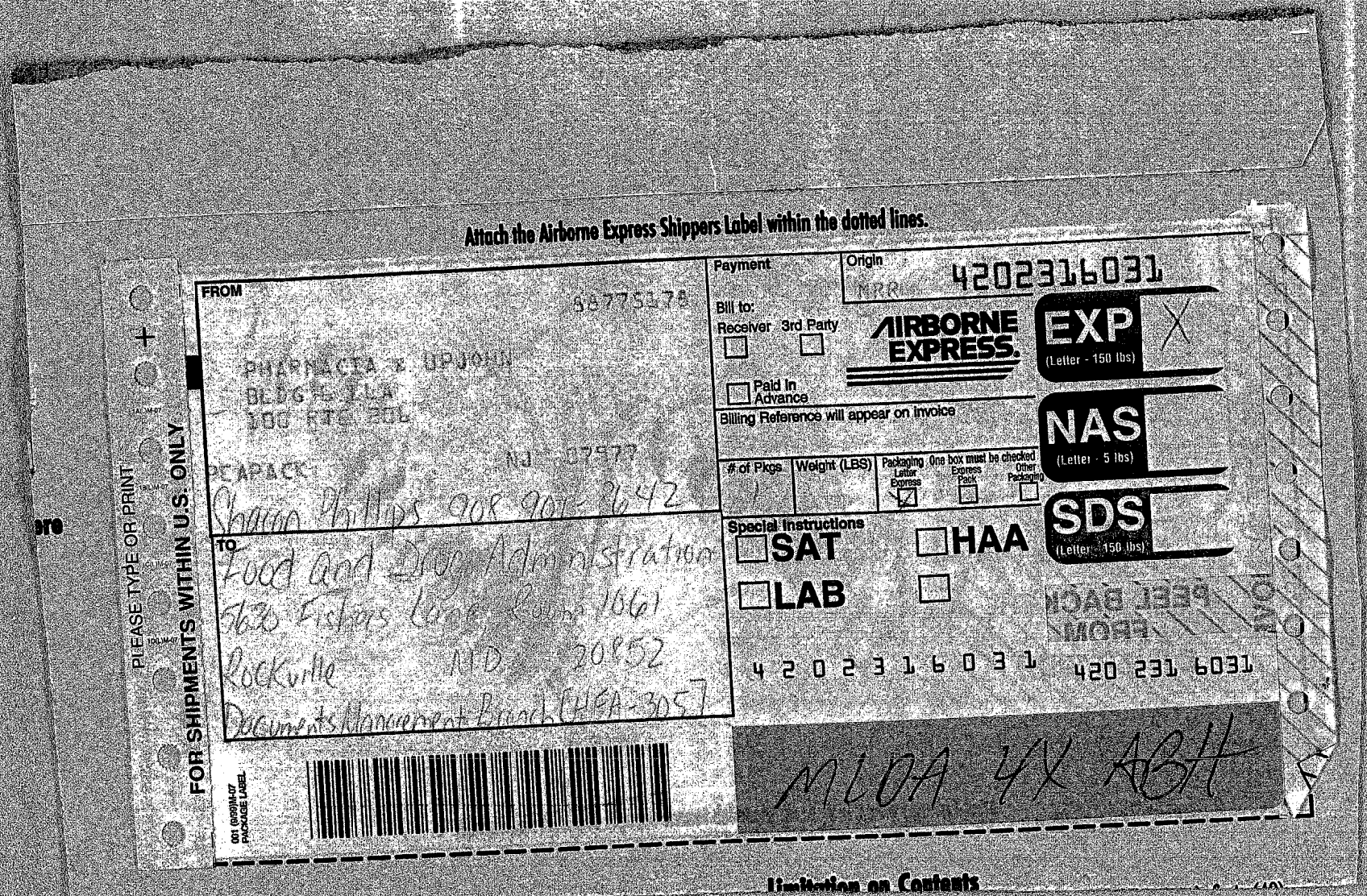
Generally, the most frequently reported drug-related side effects are not specified in the patient or physician labeling and adverse event tables report events regardless of causality. Also, the incidence threshold for reporting adverse event data from clinical trials varies among products. For example, some adverse event tables report events at an incidence of ≥ 1% others at ≥ 5%, depending on such factors as patient population and disease state studied. Because of this variability, Pharmacia recommends using the adverse event tables in the physician package insert to establish the most frequently reported side effects for each product when the physician insert doesn't specify the most frequently reported drug-related side effects. Additionally, Pharmacia recommends that any side effect classified as "most frequently reported" have an incidence greater than that reported for placebo in clinical trials.

With the publication of this draft guidance it appears that criteria have been/will be established for the use of FDA-approved patient labeling as a brief summary for consumer directed print advertisements. Based on the information FDA is allowing to be used to fulfill the brief summary requirement for patient-directed material, Pharmacia recommends that FDA revisit 21 CFR 202.1(e)(3)(iii) and propose similar modifications.

Pharmacia appreciates the opportunity to provide comment on this draft guidance and looks forward to continued dialogue with the FDA on DTC advertising issues.

Sincerely,

Sharon S. Phillips



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