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Documents Management Branch
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

February 14, 2007

Re: Direct-to-Consumer (DTC) Print Size Readability

The undersigned submits this Petition under Section 21 CFR 10.20 and 21 CFR 10.30 and other pertinent sections of the Federal Food, Drug and Cosmetic Act or any other statutory provision which authority has been delegated of the Commissioner of Food and Drug to request the Commissioner of FDA to standardize and increase print size for direct-to-consumer advertising for readability of patients and consumers. Many of these ads are for prescription drugs, over-the-counter drugs and herbal dietary supplement drugs.

This Petition requests the FDA Commissioner to issue a Federal Regulation to increase print size of direct-to-consumer advertisements.

Some of the scientific facts which require immediate action on this Petition are as follows:

1. Prescription drugs and over-the-counter medicines along with herbals are used safely and effectively by patients and consumers.

2. Direct-to-consumer advertising has increased from less than one billion dollars in advertising four years ago to over 6.5 billion dollars today.

3. Many of the ads in newspapers and magazines have print size too small for consumers and patients to read.

4. The successful use of prescription drugs and over-the-counter medicines is self-care and is due in large part to labeling, which includes information needed for proper use of the product. The label includes: the name and identity of the product; what the product will do; net contents; active ingredients; inactive ingredients; name and location of the manufacturer, distributor or picker; directions for use; warnings; and where applicable; side effects, drug interactions, and circumstances under which a doctor's advice should be sought. If the above information is printed in direct-to-consumer advertising too small for the patient/consumer to read, this information is useless.

5. Readability describes the ease, speed and accuracy with which information on direct-to-consumer advertising can be read.

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6. No single factor can of itself determine readability. Many factors interact and

the total effect of all the factors must be considered. For example, in direct-to-consumer advertising, type size, line length, and leading "spacing between lines" interact in a complex way and therefore should be selected in relation to one another.

7. The advertising designer of direct-to-consumer ads needs to be aware of the effect of the factors inherent in the production of the direct-to-consumer advertising. These include: a. the ink used; b. the substrate (material on which the copy is printed); c. the final size of the direct-to-consumer advertising; d. the final size of the type; e. the process used to create the printed direct-to-consumer advertisement.

8. The final judgment on the readability of the direct-to-consumer advertising should be made by a human being, or several, who are sensitive to the factors that go into good readability.

9. An individual or project team of several people, representative of consumers, should be designated to serve as readability evaluators.

10. Many technical factors effecting direct-to-consumer readability need to be considered: a. Layout and design; b. Typography in printing; c. Columns vs. broken lines; d. in boxes.

11. Special paragraphs need to portray most importantly drug interactions, side effects, cautions, black box warnings and special advice to patients and consumers. This information should be in the first part of the direct-to-consumer advertisement makeup.

12. Type size and spacing along with contrast, brightness and color sometimes makes it almost impossible for seniors to read and understand (see enclosed eleven ads).

ACTION REQUESTED:

PPSI requests the FDA to immediately increase print size on direct-to-consumer advertising for patient's and consumer's readability.

PPSI strongly believes FDA needs to act NOW.

Seniors encompass 13% of the total population in the US; however, seniors use 43% of all prescription drugs and over-the-counter medicines along with herbal supplements.

PPSI believes there is ample amount of scientific evidence and information available along with the enclosed original ads to justify this immediate action.

Over 770,000 US citizens go to hospital emergency rooms due to adverse drug reactions, drug interactions, allergic reactions and in many cases the patient receives the wrong medication or incorrect dosage. This could be avoided if direct-to-consumer advertisements are readable and understandable especially for patients and consumers.

PPSI praises those ad agencies who put direct-to-consumer ads out (see ad No. 1 for Lyrica by Pfizer). Notice the important facts and how easy they are to read. All direct-to-consumer advertisements should be like this which gives the important facts in a box and bold form so patients and consumers are able to read and understand them.

There is no environmental impact associated with this Citizen's Petition and we wish to be excluded under 21 CFR Sec. 25.24.

There is no economic impact involved with this Citizen's Petition and according to a recent study there would be a thirty-three billion dollar savings on decreasing costs in hospital, emergency room and doctor's visits along with the untold lessening of unneeded deaths due to adverse drug reactions, side effects, allergies and basic information on safety issue in direct-to-consumer advertising.

The undersigned certified, that, to the best knowledge and belief of the undersigned this Petition includes all information and view on which the Petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the Petition (21 CFR Sec. 10.30b).

Signature

Name of Petitioners: **Frederick S. Mayer, R.Ph., M.P.H.**
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cc: Deborah Platt Majoras, Chairman, FTC
Steve Galson, M.D., MPH, Director, CDER, FDA

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Deborah Platt Majoras, Chairman
FTC
6th & Pennsylvania Avenue
Washington, DC 20580

Steve Galson, M.D., MPH
Director, CDER
FDA, 5515 Security Lane
Rockville, MD 20857

RE: DIRECT-TO-CONSUMER ADVERTISING
PRINT SIZE READABILITY

Dear Ms. Majoras and Dr. Galson:

Pharmacists Planning Service, Inc. (PPSI) is a 501 C (3) nonprofit public health, consumer, pharmacy education organization is greatly concerned about the direct-to-consumer (DTC) print size readability and the ability for patients and consumers who read these ads to understand them. These ads basically are for prescription drugs and in many cases are promoting the prescription drugs but patients and consumers are not able to read them.

I am sending you a series of advertisements from various magazines. Please note the difficulty patients and consumers have in reading them, especially seniors, who are only 13% of the population but use 43% of all prescription drugs, over-the-counter (OTC) drugs and herbals.

In 1990 PPSI petitioned FDA on label readability guidelines and introduced legislation in California to increase the print size for patients and consumers to improve the readability on nonprescription medicine labels. California Assembly Bill 2713 was signed into law by the Governor and was enacted regarding print size on OTCs. In October, 1990 the Nonprescription Drug Manufacturers Association (NDMA) put out label readability guidelines after two years of study from a task force entitled "Draft Guidelines for Maximizing Label Readability". I am enclosing a copy of the Label Readability Guidelines by NDMA.

PPSI requests that FTC and FDA get uniformity and guidelines for readability for direct-to-consumer advertising so that patients and consumers, especially seniors, are able to read prescription drug advertisements.

Under separate cover, I would like to submit a Citizen's Petition regarding direct-to-consumer (DTC) advertising and print and label readability in the current advertising of prescription drugs, over-the-counter (OTC) drugs, herbals and alternative medicines, etc.

Sincerely,

Fred S. Mayer, R.Ph., M.P.H.
President

Enclosures