

January 26, 2009

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: Docket No. FDA-2008-N-0595, Agency Information Collection Activities;
Proposed Collection; Comment Request; Experimental Study: Toll-Free Number
for Consumer Reporting of Drug Product Side Effects in Direct-to-Consumer
Television Advertisements for Prescription Drugs**

Dear Sir/Madam:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the experimental study: Toll-free number for consumer reporting of drug product side effects in direct-to-consumer (DTC) television advertisements for prescription drugs. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

ASHP keeps health-system pharmacists informed of drug safety issues and helps them respond appropriately by publishing drug information for health professionals and consumers, promoting evidence-based medication-use programs, and publishing reports of adverse drug events in the *American Journal of Health-System Pharmacy*. ASHP became a MedWatch partner at the inception of that program and continues to disseminate MedWatch notices via its Web site and NewsLinks to ensure the Society's members provide the safest and most effective patient care.

ASHP policy supports DTC advertising that is educational in nature about prescription drug therapies for certain medical conditions and that appropriately includes pharmacists as a source of information. ASHP further supports DTC advertising of specific prescription drug products only when the following requirements are met:

1. That such advertising is delayed until postmarketing surveillance data are collected and assessed;
2. That the benefits and risks of therapy are presented in an understandable format at an acceptable literacy level for the intended population;

3. That such advertising promotes medication safety and allows informed decisions; and
4. That a clear relationship between the medication and the disease state is presented.

ASHP also believes televised DTC advertisements should include a statement encouraging consumers to report side effects of prescription drugs to MedWatch.

Recommendations

Overall, ASHP is pleased with the proposed study that will examine the placement of the toll-free statement and the length of time the statement is presented on-screen in a DTC television advertisement for a prescription drug. The study will also examine potential differences in comprehension based on the wording of the toll-free statement and the prominence of the statement. In order to enhance the quality, utility, and clarity of the information collected, ASHP makes the following recommendations regarding statement placement, statement wording, and study procedure:

1. *Statement Placement* - ASHP supports FDA's plans to assess comprehension in relation to placement of the toll-free statement, but the Society does not believe the statement is best placed after the risk information. Ideally, the statement should appear onscreen with the announcement of non-life threatening or minor side effects. Discussion of life threatening side effects that necessitate medical attention should be clearly distinct in time and placement from the MedWatch statement. ASHP encourages FDA to give equal consideration to each of the placements that have been proposed.
2. *Statement Wording* – FDA plans to test two statements, however neither of the statements will assess whether a patient can differentiate between a serious and a non-serious side effect. While a statement that contains this additional language would likely increase the complexity of the wording of the advertisements, it is important to determine whether patients fully understand the type and severity of an adverse drug event that would necessitate seeking immediate medical attention (for example, difficulty breathing), versus an event that should simply be reported to FDA (for example, a headache).
3. *Procedure* – The study design includes questions posed to participants during a structured interview. ASHP recommends that this study design also include a simulation study, where participants are asked to demonstrate how they might respond to and differentiate between minor and severe side effects. A simulation study would provide more accurate information regarding how a patient would likely respond to side effects.

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The Society appreciates this opportunity to present its written comments on the experimental study. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at jcoffey@ashp.org.

Sincerely,

A handwritten signature in cursive script that reads "Justine Coffey".

Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs