June 5, 2006

Federal Trade Commission
Office of the Secretary
Room H-135 (Annex J)
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Re: Authorized Generic Drug Study: FTC Project No. P062105

Dear Secretary Clark:

AARP has a longstanding commitment to promoting prescription drug affordability for Americans age 50 and older. We are pleased to comment on the proposed collection of information for your study of the competitive effects of authorized generics on the prescription drug marketplace.

We believe that the study, as described in the notice, will greatly assist the Federal Trade Commission (FTC) in its important roles of advising Congress and regulatory agencies, safeguarding principles of fair competition, and providing economic analysis on key consumer marketplace issues.

Rising prescription drug costs continue to be a real financial burden for Americans of all ages. For example, the required cost-sharing for millions of Medicare beneficiaries who have enrolled in the new drug program is linked to rising drug costs. Some of the estimated 45 million Americans who lack health insurance choose to forgo medicines completely because they cannot afford the cost. For these most vulnerable consumers, the difference between drug prices with real generic competition and those arising under purported 'competition' of authorized generics may translate into tangible barriers to access.

AARP's "Rx Watchdog Report" tracks the prices of commonly used prescription drugs for older adults. Our "Watchdog Report" has found that the prices manufacturers charge for brand-name prescription drugs outpace inflation, sometimes more than two to one. In contrast, our most recent "Watchdog Report" found that none of the 75 generic drugs most widely used by older Americans had a change in manufacturer list price during the second and third quarters of 2005.

It is important to note that the relatively recent practice of authorized generics is just one growing trend in the industry's arsenal of anticompetitive practices. The Medicare Modernization Act of 2003 (MMA) included provisions to ban one such practice, that of filing consecutive 30-month stays, by limiting brand-name manufacturers to a single 30-month stay. However, brand-name pharmaceutical manufacturers facing the loss of patent protection on blockbuster drugs use multiple tools, including "evergreening" or extending the patent protection of a brand name prescription drug as the term of the original patent nears expiration; filing sham citizen petitions; and abusing the declaratory judgment system.

When viewed in total, such practices seriously erode the ultimate goal of the Hatch-Waxman Act, which was to increase competition in the pharmaceutical marketplace by speeding up the approval for generic drugs.

The notice invites comments on five specific information requests that will form the basis of the FTC study. We encourage the Commission to broaden the scope of the study to also examine the impact of authorized generics on consumers. In particular, we urge the Commission to:

- assess how different generics offer different levels of savings over the brand name drug;

- examine whether, in order to get better prices, consumers must search for a generic not produced by the manufacturer of the brand name drug;

- examine the cost impact of authorized generics on public programs, such as Medicare and Medicaid, and on private health insurance; and

- assess how the use of authorized generics impacts access to lower cost generic drugs, particularly for low-income individuals.

We believe that by expanding the scope of the study, the FTC will be able to provide a much clearer picture of the effects of authorized generic drugs on the marketplace.

Sincerely,

David Certner
Legislative Council and
Legislative Policy Director
Government Relations and Advocacy