February 22, 2007

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

Re: Prescription Drug User Fee Act: Proposed Recommendations for Reauthorization
72 Fed. Reg. 1743 (January 16, 2007)

To Whom It May Concern:

AARP appreciates the opportunity to comment on the FDA's proposed recommendations for the reauthorization of the Prescription Drug User Fee Act (PDUFA). AARP represents 38 million Americans aged fifty and older. Older Americans use prescription drugs more than any other segment of the U.S. population; thus, access to and safety of these medicines are of great concern to our organization.

In general, AARP is concerned with the high level of vital FDA funding that is generated through a user fee program. We believe that the safety and efficacy of prescription drugs is a societal good, and thus sufficient federal funding should be appropriated to lessen the agency's dependence on user fees.

Postmarket Drug Safety System

Under PDUFA III, the FDA was given the authority to collect user fees for drug safety review. However, the language of the Act restricted the period of time under which the FDA can spend these user fees for drug safety activities. If such activities fall outside the statutory timeline, then they must be funded with appropriated dollars. AARP supports FDA's recommendation to remove the timeline under which FDA can spend user fee dollars for drug safety review. AARP believes that the safety of prescription drugs is paramount and that FDA should have the authority necessary to conduct all matters of postmarket review to ensure the safety and efficacy of prescription drugs. AARP also supports a more equitable distribution of resources between pre-marketing and post-marketing review functions by the agency.

The FDA proposes to expand database resources for adverse event detection and risk assessment. AARP applauds this proposal. Now that the Medicare prescription drug benefit has been implemented, we encourage the FDA to use

data collected under the Medicare Part D program to conduct drug safety reviews. The claims data from the Medicare program will provide a wealth of data from which to discover adverse events more quickly. Timely data-exchange between FDA and the Centers for Medicare and Medicaid services could greatly enhance post-marketing surveillance, thereby promoting safe prescribing and utilization of prescription medicines.

In addition, the FDA proposes to use part of the user fees to conduct public discussion and review of risk communication and management. Currently risk communication and management is not being presented in a manner that is useful to consumers. AARP applauds the FDA for their proposal to engage in an open dialogue on this much-needed topic. However, we are concerned with the proposed pace of the "annual systematic public discussion and review." Under the FDA's proposal, only one-to-two risk management programs and "one major risk management tool" would be evaluated per year. Public identification of criteria by which associated drugs (and their risk management programs and/or tools) will be selected will be very important to ensure that such review is a worthwhile exercise. Further, FDA-mandated tools such as Medication Guides and FDA-Developed Patient Information Sheets should be included in the spectrum of review of effectiveness. In addition, the proposal calls for reports "from these discussions" to be posted on the FDA website. AARP urges the FDA to expand the proposed dissemination plans to include targeted outreach to national and state medical organizations, other prescriber groups, pharmacy associations, and providers of continuing medical education. Further, FDA may want to consider focus group testing of the patient information sheets and any other materials that will be made available to consumers.

Finally, the FDA proposes to modernize the proprietary name review program. As the Institute of Medicine (IOM) study found, one common cause of medication errors is the similarity of prescription drug names. Prescription drug names often look and sound alike, which can be confusing for consumers. These problems are often exacerbated by other factors such as unclear labeling, use of suffixes, etc. AARP supports the FDA's efforts to reduce errors by developing guidance on the proprietary name review program. We also believe that the agency should have stronger enforcement authority when unsafe naming practices persist within the industry. Further, consumers should be included in the development of this guidance.

Separate User Fee for DTC Television Ads

FDA proposes a new, separate user fee program for review of direct-to-consumer (DTC) television advertisement. This user fee program would be completely voluntary and would not extend beyond television advertisements.

Under this proposal, the user fees would be comprised of a one-time assessment (which is intended to fund a $6.25 million reserve fund) and annual fees (which would be based on the number of anticipated submissions).

AARP is pleased to see that FDA is proposing to be more vigilant in the area of direct-to-consumer advertising. Some DTC advertising is helpful to consumers, particularly when it provides information about a disease or condition (e.g., help seeking advertisements). However, much of the DTC advertising is product-specific and may not be helpful to consumers. While we recognize that the industry adopted its own voluntary guidelines two years ago, AARP believes that the FDA, not the industry, should regulate direct-to-consumer advertising. We would like to see the FDA, working in consultation with other interest groups (including consumers and providers) revise its 1997 "Guidance for Industry: Consumer-Directed Broadcast Advertisements."

AARP believes that the FDA should be granted the authority to mandate that all drug advertising – not just television advertising – should be subjected to prior approval by the FDA. Under the proposal as set forth, we question industry's willingness to participate in a voluntary review program. We note that under the proposal, industry can pick and choose which advertisements it would like to submit to the approval process. This is problematic and we fear it will do little to stem harmful DTC advertising. Moreover, AARP believes that pre-clearance of television advertisements can only go so far. We believe that the FDA should examine the benefit of requiring a two-year moratorium on DTC advertising to consumers on all newly-approved prescription medicines. This would permit the agency to accumulate and evaluate post-marketing safety data based on general population use of the product.

AARP appreciates the opportunity to submit comments on FDA's proposed recommendations on PDUFA reauthorization. If you have any questions or need additional information, please feel free to contact me, or please contact Anna Schwamlein Howard of our Federal Affairs Department at 202-434-3770.

Sincerely,

David Certner
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Government Relations and Advocacy