June 20, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20857

Re: Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels
Docket No. 00N-1269
65 Fed. Reg. 81082 (December 22, 2000)

Dear Sir or Madam:

AARP is pleased to submit these comments on the Food and Drug Administration's (FDA) proposed rule on physician labeling for prescription drugs. We commend the FDA for its continued efforts to improve the content and format of drug labels and labeling -- in its Medguide rule, the new OTC drug label, and now with this proposal to improve the drug packet inserts that accompany prescription drugs. Redesigning these inserts to make them easier to use could help reduce the rate of medical errors associated with improperly prescribed prescription medicines. While these inserts are directed to health care professionals, they are also used by many consumers and, as a result, these redesigned leaflets could help improve compliance with prescription drug regimens.

While AARP generally supports the proposed regulation revising the content and format of physician labeling, we have two concerns. First, we seriously question FDA's decision to limit the application of the new format requirements to those drugs and biologics approved within 5 years of the effective date of the final rule. The agency bases this tentative decision on a number of assumptions, including its belief that physicians are more likely to refer to the labeling of recently approved products than the labeling of older products, that the labeling of recently approved drug products is likely to be longer and more complex, and that older products will be subject to the new format requirements once they submit efficacy supplements. It is unclear whether these assumptions are based on any empirical evidence, and at least one is questionable on its face: the agency's assumption that physicians are more likely to refer to the labeling of recently approved drugs than older drugs fails to recognize that while this may be true for experienced physicians, it may not be the case for new doctors and other health care professionals.

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AARP is troubled by the fact that if the new format requirements are applied as proposed, then physician labeling for only one of the top 15 prescription drugs used by the elderly would be required to be printed in the new format.[1]

Since older persons comprise the largest group of consumers who regularly take prescription medications, with many of them taking multiple drugs at the same time, FDA's proposed decision to limit the application of the new format requirements as it has seriously undermines the new rule's effectiveness. We urge the agency to reconsider its proposed implementation schedule and revise it to ensure that the new format requirements will apply to the largest number of prescription medications possible. The decision on which prescriptions drugs should be covered by the new rule should depend not on which drugs were most recently approved, but on factors such as which drugs are most widely used and which ones may pose the most serious safety concerns (in terms of side effects, adverse reactions, and interactions).

Second, we urge FDA to reconsider its tentative decision to set the minimum type size for drug package inserts at 8-point, rather than 10-point, type. In its proposal, FDA acknowledges that the smallest recommended font size for the general public is 10-point and that 12-point type is generally recommended for older people. However, it opts for 8-point type in order to minimize the economic impact of the new format requirements. We question this choice, and whether the agency has adequately considered the greater benefit in terms of readability associated with information printed in 10-point rather than 8-point type. We believe that the difference between the two is significant.

Before finalizing its rule, AARP urges the agency to test prototypes printed in 8-point and 10-point type, on both health care professionals and consumers. Because readability does not depend solely on type size, we also suggest that FDA consider including other format requirements – type style, use of upper- and lower-case letters, leading (space between lines) and kerning (space between letters) – in its physician labeling regulation.

AARP appreciates this opportunity to comment on FDA's proposal on physician labeling for prescription drugs. If you have any further questions, please contact Patricia Smith of our Federal Affairs Staff at (202) 434-3770.

Sincerely,

Martin Corry
Director, Federal Affairs

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[1] Only Celebrex, the sixth top drug (based on number of prescriptions) used by the elderly, was approved within the five-year period. *See* Families USA, "Enough to Make You Sick: Prescription Drug Prices," Table 4, page 11 (June 2001). The table can be found at <www.familiesusa.org/drugs$$.pdf>.