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

Re: Docket No. 00N-1256

Dear Sir or Madam:

United Seniors Health Cooperative (USHC) requests that these comments be included in the record for the June 28-29, 2000, public hearing on Over-the-Counter Drug Products, in response to FDA's request for comments on questions over these products.

USHC is a non-profit organization comprised of thousands of consumers, advocates, and eldercare professionals throughout the country who are committed to the belief that informed consumers are those best able to help themselves. USHC is a leading source of accurate, unbiased information for "aging network" professionals, older consumers and family members.

Estimates are that older adults, those age 65 and up, make up 13% of the population, yet they account for at least 25% of OTC medicines used. One reason for the more frequent use of OTCs among older adults is that many conditions for which OTC drugs are used, including chronic conditions, become more prevalent with advancing age. The lack of a drug benefit for many older Americans makes the easy access and competitive prices of nonprescription drugs even more important.

The trend of switching drugs from prescription-to-nonprescription provides older Americans with more choices for their conditions, including a broader selection of pain relievers and digestive products such as the acid blockers. If FDA's public hearing serves to further this switch trend, it will be a welcome sign.

But as FDA looks at this area, a number of areas remain important:

- A wide margin of safety must be maintained for OTC medicines, including thorough labeling needed for safe use. As we look at the marketplace today, FDA has historically done a commendable job in

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- this area, as evidenced by the strong safety track record of products switched to OTC drug status thus far. To continue this individual drug safety emphasis, USHC believes FDA should remain focused on the specific drug candidate, rather than prejudging a candidate based on the disease or condition the drug is used for.
- For all consumers, especially older adults, it is important that labels be easily understood. It is particularly appropriate for new OTC drugs to be designed in a consumer-friendly way and it makes sense that the company that knows the most about a drug should drive the label studies needed to support the switch to OTC drugs. We do not believe FDA itself, nor an outside party, should lead this process.
- Last, FDA asks whether OTC drugs should be sold "behind the counter." This type of closed approach would reduce the convenience American consumers expect and deserve for OTC drugs, and would lessen some of the competitive pressure that helps keep OTC drugs affordable for older adults. Such a move would also run against FDA's own past policy statements that there is no public health need for such a system, and would contradict conclusions of a U.S. General Accounting Office report five years ago: "Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Determined."

Thank you for the opportunity to provide these views and USHC looks forward to seeing more opportunities develop in self-medication for all consumers, including older adults.

Sincerely,



Anne Werner
President & CEO