OTC Monograph User Fee Public Meeting
Remarks of Cynthia A. Bens
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Good morning everyone.

My name is Cynthia Bens and I am vice president of public policy at the Alliance for Aging Research.

I would like to thank FDA for inviting me to serve on the panel today to share some insights on the importance of over-the-counter (OTC) products in the care of older adults and provide our views on the creation of a new user fee program for monograph activities as they relate to OTC products.

For those of you who are not familiar with the Alliance for Aging Research, we are a non-profit organization based in Washington, DC. We were founded 30 years ago and since then our mission has been to support research and its application to improve the experience of aging and health.

In the early days of the Alliance, our focus was largely on advocacy for increased funding of aging research at the National Institutes of Health. This is still a core issue for us but 10 years ago we broadened the scope of our activities to include a focus on regulatory issues impacting the development of innovative medicines for seniors. Through our experience we have come to recognize the important role the FDA plays in encouraging innovation and enabling access to safe and effective products for seniors.

The Alliance for Aging Research also maintains robust health education programs that provide educational materials for patients, caregivers and health care professionals about diseases and conditions of aging. In the last year, we developed short animated films on the safe use of OTC pain medications by older adults and the use of dietary supplements as part of nutrition in healthy aging. Our materials can be found on the Alliance's website, www.agingresearch.org.

Most of us are keenly aware that our population is aging at an unprecedented rate. 10,000 Baby Boomers are turning 65 each day. This is up from 6,000 per day just 5 years ago.

People age 80 and older now make up the fastest growing segment of our population.

About 10% of the US population is 80 or older and that number will triple by the middle of this century.

The good news is that many people are living healthier as they age. But the unfortunate truth is that most older adults still face significant periods of illness and disability later in life. They experience forms of cardiovascular disease, cancer, diabetes, bone and joint degeneration, muscle wasting, vision and hearing loss, neurological diseases, persistent pain, and incontinence.

Many of these ailments are treated with prescription drugs, medical devices, and lifestyle interventions, but older adults also rely heavily on non-prescription OTC medications as part of their regular care. While the FDA decides whether a medicine is safe enough to sell over-the-counter, taking OTC medicines still has risks. Some interact with other medicines, supplements, foods or drinks. Others cause problems for people with certain medical conditions.

There are approximately 100,000 OTC products on the market today. U.S. consumers spend as much as $32 billion on these products. Older adults use OTC medications more than any other demographic group, accounting for 30% of all OTC medication use.

Primarily older adults use non-prescription OTC products to relieve pain, reduce GI disturbances, help with sleep, and maintain oral health. Proper use of these products is essential, and can represent substantial cost savings to individuals and to the healthcare system. The Consumer Healthcare Products Association estimates that OTC products provide as much as $102 billion in value to the healthcare system with $77 billion saved in unnecessary office visits and diagnostic tests and $25 billion dollars in savings on prescription drug costs.

Many of the OTC non-prescription medications in routine use by seniors are monograph products. They were marketed this way because they contain ingredients that were determined to be generally safe and effective for use in self-treatment. OTC monographs are continually updated by the FDA to add, change, or remove ingredients, alter labeling, or include other pertinent information. Despite the significant role OTC monograph products play in routine care, FDA's review of ingredients included in and proposed for inclusion in OTC monographs is underfunded. With 30FTEs and $8 million devoted to these FDA activities, a lack of funding has contributed to unfinished monographs and delayed labeling changes. We fear that this could have negative consequences for public health and safety.

The Alliance for Aging Research has observed the success of user fee programs in expediting access to safe and effective prescription drugs and medical devices for seniors. The prescription drug and medical device user fee programs came about to

add speed and predictability to the drug and device review processes. PDUFA and MDUFA allow the FDA to maintain adequate staffing levels for timely product reviews and establish transparent metrics to hold the agency accountable for meeting certain performance goals.

While we recognize that not all OTC products go through the same pre-market review process as drugs and devices, we feel that the same principles of these programs can benefit the regulation of OTC products by expanding FDA's capacity in a targeted way, allowing the agency to fill highly-skilled vacancies, and scoping out other defined areas where fees would have the greatest impact.

OTC products will play an increasingly important role in self-care, as our population continues to age. Realizing the benefits of safe and effective OTC products will only be possible if FDA has access to the resources necessary to evaluate them. The Alliance continues to engage in user fee discussions because we understand that user fees play an essential role in maintaining regulatory processes that efficiently deliver safe and effective products for people who need them. We are generally supportive of FDA's desire to institute a user fee program for OTC monograph activities.

Our first recommendation is that the user fee program be developed through monthly consultation with patient groups, consumer groups, and industry. We have seen this type of multi-stakeholder engagement work well in both the inception and reauthorization of current user fee programs. We believe that this engagement at the front end can ensure that an OTC monograph user fee program has the intended effect of providing more certainty and timeliness in the monograph process.

Our second recommendation is that the proposed user fee program not exceed the amount of appropriated resources devoted to the OTC monograph activities. The Alliance for Aging Research is a leader of the Alliance for a Stronger FDA which advocates solely for appropriated funding for the FDA with strong emphasis on finding a balance between user fees and appropriated funding. We believe that this balance is critical because FDA is a public health agency at its core and its mission is to serve the interests of the American public. If the user fee program does move forward, the Alliance for Aging Research believes that it should start small and be clearly defined.

Finally, while the prescription drug user fee program has been successful in many ways, we offer a note of caution. The amount of PDUFA fees increases with each reauthorization and user fees now account for between 60 and 70 percent of all human drug review activities at the agency. The Alliance for Aging Research feels that user fees should not replace appropriated dollars or become a dominant funding source for the agency because they are targeted by nature and do not allow the FDA the flexibility to adapt to changing science. For this reason, we recommend that the agency and industry agree to a period of time to re-evaluate the need for the OTC user fee program.

I'll close by saying that we know that this meeting is the start of an ongoing process of soliciting input from various stakeholders so we welcome the opportunity to provide additional information to the agency as appropriate. Thank you for your attention and again thank you to FDA for the allowing me to comment today.