Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville, MD 20852

Re: FDA-2014-N-1698, FDA Activities for Patients Participation in Medical Product Discussions

On behalf of the more than 50 million adults and children living with arthritis in the United States, the Arthritis Foundation welcomes the opportunity to comment on activities for patient participation in medical product discussions. People with arthritis rely on a large range of medical products, from over-the-counter pain relievers to complex biologic medications. Each person with arthritis has unique treatment needs and experiences, and the patient perspective is vitally important to inform FDA and other stakeholders of the challenges and interactions they experience with medical products. In preparation for these comments, the Arthritis Foundation surveyed over 300 people with arthritis, and found that while less than 5% of the respondents have engaged with FDA, over 90% of them would like to.

As you know, arthritis is not one disease, but rather an umbrella for more than 100 different diseases, from osteoarthritis to auto-immune forms of the disease like rheumatoid arthritis, inflammatory forms of the disease like ankylosing spondylitis, and even infectious forms of the disease like that caused by Lyme's disease. The heterogeneity of arthritis can make it difficult to diagnose and treat. People with complex forms of arthritis like rheumatoid arthritis often have to try many treatments before finding the one that works best for them. There are demographic challenges as well. More women get auto-immune forms of arthritis than men, and on-set usually occurs during their reproductive years, presenting a unique set of challenges s about the effects of drugs during pregnancy. In addition, approximately 300,000 children have arthritis. They often require complex treatments, presenting questions about the long term impacts of medications. Finally, the sheer prevalence of the disease – it affects 1 in 5 Americans – means that people with arthritis make up a significant portion of the U.S. population that relies on FDA-approved medical products.

The Arthritis Foundation believes that the approval of biosimilars is an example of an opportunity for patient engagement. Many people with auto-immune forms of arthritis rely on biologic medications to manage their disease. For them, biosimilars may hold great promise in providing new choices in disease treatment. However, patient safety is of the upmost importance to the Arthritis Foundation community as biosimilars enter the market. Patient education and adverse event tracking are two major aspects of patient safety. Since the first biosimilar applications have been accepted by the FDA, this is an opportune time to engage patients on biosimilars, including how they are different from originator biologics, and what safeguards are in place as they enter the marketplace.

We believe there are a number of ways that the FDA can facilitate patient engagement:

<u>Two-way communication mechanisms</u>

To accomplish the goals of the FDA's Patient Preference Initiative, it is important to have two-way communications mechanisms in place. We would encourage the creation of a patient portal on the FDA website where patients can get trusted clinical information and can provide informative comments on these treatments and engage directly with the FDA.

Patient education about new treatments like biosimilars will be of critical importance to patients. Patients generally know what medications they are taking, and what the benefits and potential side effects are. The Arthritis Foundation is suggesting a patient portal that provides patients the opportunity to communicate with the FDA about experiences with new drug classes like biosimilars and would provide the FDA with timely feedback on the patient experience.

Another finding from the Arthritis Foundation survey is that patients want more education on medical products. One respondent commented that patients are often the last to know about the development of new drugs, but they should be the first to know. Another respondent commented that the more involved patients are at each step, the more they will know what to look for when drugs come to market. In general, the respondents felt it is important for the FDA to talk to patients about what their needs are and how patients feel about medications before drugs come to market.

In our survey, respondents listed several ways they would like the FDA to include them in the drug development process. These include emails, webinars, surveys, and focus groups. Specific requests for patient education include: reasons some medications are not FDA approved, basic information on the drug development process, and more information on differences between similar drugs. Several respondents also requested ways to inform the FDA of their experiences with medical products, including through a hotline they can call into when issues arise.

The Arthritis Foundation can also facilitate patient data collection and is ready to assist the FDA in gathering information on the perspectives of people with arthritis on risks and benefits of medical products. In addition, several survey respondents suggested the creation of an arthritis patient panel or advisory group to help provide FDA with information on patient experiences and perspectives on medical products. The AF could help facilitate the creation of such a panel or advisory group.

<u>Stakeholder collaboration</u>

The AF is the largest non-profit organization representing the interests of people with arthritis, and therefore is a primary conduit for reaching people with arthritis. Though the FDA has a number of resources for patients, including post-market drug safety information, medication guides, podcasts and a blog, it is unclear the extent to which patients utilize that information. We encourage the FDA to increase its collaboration with the AF and other organizations that have direct connections with patients. Examples of collaboration can include:

- The AF can include FDA updates and FAQ's in newsletters, including the Advocacy in Action newsletter which reaches over 80,000 people. An FAQ to help people with arthritis understand the many nuances of biosimilars would be particularly beneficial.
- The FDA can conduct tele-townhalls with the AF community on new developments in drugs that affect people with arthritis.
- The AF can share FDA webinars or videos with people with arthritis, including through newsletters and the website.

As the FDA considers guidance and regulations that affects people with arthritis, the AF would like the opportunity to meet with the FDA on behalf of the patient community. We appreciated the opportunity to meet with FDA staff on biosimilars in October 2014, and we would like to make these types of meetings a more regular occurrence.

Patient-focused drug development meetings

We applaud the FDA for initiating a series of meetings on patient-focused drug development. Arthritis is not currently included in the list of meetings. Given the complexity of the disease and the many types of medical products that people with arthritis rely on, we encourage you to include arthritis and its related diseases like lupus as a topic. The AF would like to be a partner in this program, and would employ various communications strategies to ensure robust attendance and participation in the meeting.

Thank you for the opportunity to comment on patient participation in medical product discussions. The Arthritis Foundation and our community of advocates welcome future opportunities to engage with the FDA on issues of importance to people with arthritis. Should you have any questions, please contact Sandie Preiss, Vice President of Advocacy and Access, at 202-887-2910 or spreiss@arthritis.org.

Sincerely,

Sandie Preiss