MSAA™
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October 14th 2013
Office of the Center Director
Janet Woodcock, MD
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Dr. Woodcock:

We are writing to you today to request an opportunity to have a public meeting with key stakeholders to help understand the issues related to biosimilars and non-biologic complex drugs for MS patients. The Multiple Sclerosis Association of America has focused its efforts since its inception in 1970 on educating, advocating and providing support for people with MS, their care partners and the healthcare professionals who serve them. We are a founding member of the MS Coalition, which is comprised of eight national MS patient advocacy organizations, all committed to collaboration and cooperation providing high quality information and services to the MS constituency.

This subject is receiving significant increased attention and MSAA has an obligation to provide fair, balanced and informed information and education about such issues. Our goal is to assimilate the "state of the art" current knowledge from all parties (health care professionals, FDA, the pharmaceutical industry, insurers, and others). A public advisory forum would facilitate an excellent opportunity to learn and educate patients.

To present the most up-to date and complete information on this topic, we need your help. Our synopsis will likely focus on efficacy and safety related to biosimilars and non-biologic complex drugs. We need to understand and articulate the concepts of biosimilarity and "interchangeability" to the MS community. How will these concepts be determined? What are the implications for MS patients?

The FDA has shown its commitment to solicit patient and patient advocacy input and perspectives. We would like to work with the FDA on formulating a fair and balanced approach to this important subject. The MSAA stands ready to lead a broad based community effort to help MS patients understand these important issues.

I look forward to your response and a productive collaboration on this important project.

Yours sincerely,

Douglas G Franklin
President & Chief Executive Officer
Multiple Sclerosis Association of America

President
MS Coalition

The Multiple Sclerosis Association of America and the National Multiple Sclerosis Society appreciate the opportunity to have a discussion with the Food and Drug Administration (FDA) about the development of a biosimilar pathway. Since multiple sclerosis (MS) is an indication with a significant number of FDA-approved biologics, we are concerned that the Agency's approach to this category of drugs could have significant impact on people with MS.

In order to structure our conversation together, we would be interested in hearing the Agency's perspectives on the definition and application of an interchangeable biosimilar. Potential areas of discussion include:

1) **The clinical standards for approval of a biosimilar.** What type of evidence will the FDA require to demonstrate if an agent is interchangeable? Will there be a standard protocol or is the Agency addressing this on a case-by-case basis? If the Agency is approaching this case-by-case, will the approach be consistently applied across groups of biologics with similar modes of action (e.g. Interferon beta class, Avonex®, Betaseron®, Rebif®, etc.)?

2) **Opportunities for patient input.** What opportunities will be available for patients/patient advocacy organizations to participate in an advisory capacity in the biosimilars' approval process?

3) **Protocols to ensure consistency in the approval process.** Since MS has both biologic and non-biological complex drugs (e.g. glatiramer acetate/Copaxone®) as approved disease modifying therapies, will the same or similar approval standards be applied to both generic/biosimilar versions these therapies?