

Metro International Biotech, LLC  
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# METROBIOTECH

December 1, 2021

The Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993.

Re: Docket No. FDA-2021-P-0938 - The Food and Drug Administration (FDA) is requesting information on the past use of N-acetyl-L-cysteine (NAC) in products marketed as dietary supplements.

Dear Sir/Madam:

Metro International Biotech is a privately-owned clinical-stage pharmaceutical company that has established the most comprehensive portfolio of proprietary nicotinamide adenine dinucleotide (NAD<sup>+</sup>) precursors in the world. Metro is the sole source of MIB-626, Metro's proprietary form of beta-nicotinamide mononucleotide ( $\beta$ -NMN) which is authorized for investigation as a new drug and for which substantial clinical investigations have been instituted.<sup>1</sup> As a company that has instituted publicly available clinical trials on  $\beta$ -NMN, we request that FDA take the preclusion provision of Section 201(ff) of the Federal, Food, Drug, and Cosmetic Act seriously to protect the right of companies that have spent significant time and research to develop drugs products from competition from dietary supplements that are clearly new dietary ingredients that have never filed a new dietary ingredient notification prior to the institution of substantial clinical trials.

Sincerely,

*Michael A. Willis*

Michael A. Willis, Ph.D., JD  
Corporate Counsel

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<sup>1</sup> Please note that MIB-626 can be found in 3 clinical trials when searched at [clinicaltrials.gov](https://clinicaltrials.gov/ct2/results?cond=&term=MIB-626&cntry=&state=&city=&dist=):  
<https://clinicaltrials.gov/ct2/results?cond=&term=MIB-626&cntry=&state=&city=&dist=>  
Metro is supplying the MIB-626 for all 3 of these trials.