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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration Rockville, MD 20857

December 11, 2019

Carl H. Camp President Archway Apothecary, LLC 2190 Manton Drive Covington, LA 70433

Sent via email to: matt@archwayapothecary.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA Amendment "Bulk List of Drug Substances That Can Be Used to Compound Drug Products" be modified such that Nicotinamide Adenine Dinucleotide ("NAD") remain included on the 503A list of bulk drug substances permitted to be used in compounding for a period of not less than 5 years to enable completion of additional studies as may be needed to satisfy the U.S. Food & Drug Administration ("FDA") or its safety and efficacy, which was received by this office on 12/10/2019.

It was assigned docket number FDA-2019-P-5833. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby Supervisory Administrative Proceedings Officer Dockets Management Staff FDA/Office of Operations (OO)